UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

SKAGIT COUNTY, CITY OF MOUNT VERNON, CITY OF SEDRO-WOOLLEY, CITY OF BURLINGTON, LA CONNER SCHOOL DISTRICT, AND MOUNT VERNON SCHOOL DISTRICT,

Plaintiffs,

v.

PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; TEVA PHARMACEUTICALS INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC; MALLINCKRODT PLC; MALLINCKRODT, LLC; CARDINAL HEALTH, INC.; MCKESSON CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; and JOHN AND JANE DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

2:18-cv-00120
MDL No. 2804 (N.D. Ohio)
Judge Dan Aaron Polster

Civil Action No. 1:18-op-45173

AMENDED COMPLAINT

JURY DEMAND

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I. INTRODUCTION[1]

1. The United States is experiencing the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.

2. Since 2000, more than 300,000 Americans have lost their lives to an opioid overdose, more than five times as many American lives as were lost in the entire Vietnam War. On any given day, 145 people will die from opioid overdoses in the United States. Drug overdoses are now the leading cause of death for Americans under age fifty.

3. As many state and local governments along with the federal government have recognized—including Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, Burlington, La Conner School District, and Mount Vernon School District—the opioid crisis has become a public health emergency of unprecedented levels. The opioid abuse prevalent throughout Skagit County has affected Plaintiffs in numerous ways, not only through the need for increased emergency medical services, but also through increased drug-related offenses affecting law enforcement, jails, and courts, more prevalent drug use throughout the County and Cities including in streets, buses, and parks, higher costs for prescription opioids and opioid-related insurance claims, and through additional resources spent on community and social programs, including for the next generation of Skagit County's residents, who are growing up in the shadow of the opioid epidemic.

4. Plaintiffs have been working to confront the emergency caused by Defendants' reckless promotion of prescription opioids. For example, Skagit County Population Health Trust recently convened a multidisciplinary Opioid Workgroup, which, as explained in further detail below, is comprised of a team of community leaders dedicated to taking steps to address the opioid epidemic and related public health crisis. The Opioid Workgroup's goals include

[1] Plaintiffs file this Amended Complaint without leave of Court pursuant to Paragraph 6.b. of the Court's Case Management Order One in *In Re: National Prescription Opiate Litigation*, Case No. 1:17-CV-2804 (ECF No. 232). Plaintiffs reserve the right to seek leave to amend or correct this Complaint based upon analysis of ARCOS data not yet available, and upon further investigation and discovery. Plaintiffs also reserve all rights to amend this Complaint to the fullest extent permitted by the Federal Rules and the Local Rules of the Court.

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preventing opioid misuse and abuse, treating opioid abuse and dependence, and preventing deaths from overdose.

5. But although Plaintiffs have committed considerable resources to address the opioid crisis, to fully address the crisis will require them to spend resources it does not have. It would be unfair to require Plaintiffs to bear all the costs of addressing an epidemic caused by Defendants' intentional conduct. Rather, those responsible for the opioid crisis should pay to abate the nuisance and harms they have created in Skagit County, Mount Vernon, Sedro-Woolley, Burlington, La Conner School District, and Mount Vernon School District.

6. The opioid epidemic is no accident. On the contrary, it is the foreseeable consequence of Defendants' reckless promotion and distribution of potent opioids for chronic pain while deliberately downplaying the significant risks of addiction and overdose.

7. Defendant Purdue set the stage for the opioid epidemic, through the production and promotion of its blockbuster drug, OxyContin. Purdue introduced a drug with a narcotic payload many times higher than that of previous prescription painkillers, while executing a sophisticated, multi-pronged marketing campaign to change prescribers' perception of the risk of opioid addiction and to portray opioids as effective treatment for chronic pain. Purdue pushed its message of opioids as a low-risk panacea on doctors and the public through every available avenue, including through direct marketing, front groups, key opinion leaders, unbranded advertising, and hundreds of sales representatives who visited doctors and clinics on a regular basis.

8. As sales of OxyContin and Purdue's profits surged, Defendants Endo, Janssen, Cephalon, Actavis, and Mallinckrodt—as explained in further detail below—added additional prescription opioids, aggressive sales tactics, and dubious marketing claims of their own to the deepening crisis. They paid hundreds of millions of dollars to market and promote the drugs, notwithstanding their dangers, and pushed bought-and-paid-for "science" supporting the safety and efficacy of opioids that lacked any basis in fact or reality. Obscured from the marketing was

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the fact that prescription opioids are not much different than heroin—indeed on a molecular level, they are virtually indistinguishable.

9. The opioid epidemic simply could not have become the crisis it is today without an enormous supply of pills. Defendants McKesson, Cardinal Health, and AmerisourceBergen raked in huge profits from the distribution of opioids around the United States. These companies knew precisely the quantities of potent narcotics they were delivering to communities across the country, including Skagit County, Mount Vernon, Sedro-Woolley, Burlington, La Conner School District, and Mount Vernon School District. Yet not only did they intentionally disregard their monitoring and reporting obligations under federal law, they also actively sought to evade restrictions and obtain higher quotas to enable the distribution of even larger shipments of opioids.

10. Defendants' efforts were remarkably successful: since the mid-1990s, opioids have become the most prescribed class of drugs in America. Between 1991 and 2011, opioid prescriptions in the U.S. tripled from 76 million to 219 million per year.[2] In 2016, health care providers wrote more than 289 million prescriptions for opioid pain medication, enough for every adult in the United States to have more than one bottle of pills.[3] In terms of annual sales, the increase has been ten-fold; before the FDA approved OxyContin in 1995, annual opioid sales hovered around $1 billion. By 2015, they increased to almost $10 billion. By 2020, revenues are projected to grow to $18 billion.[4]

11. But Defendants' profits have come at a steep price. Opioids are now the leading cause of accidental death in the U.S., surpassing deaths caused by car accidents. Opioid overdose

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[2] Nora D. Volkow, MD, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Appearing before the Senate Caucus on International Narcotics Control, NIH Nat'l Inst. on Drug Abuse (May 14, 2014), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[3] *Prevalence of Opioid Misuse*, BupPractice, https://www.buppractice.com/node/15576 (last updated Mar. 16, 2018).

[4] *Report: Opioid pain sales to hit $18.4B in the U.S. by 2020*, CenterWatch (July 17, 2017), https://www.centerwatch.com/news-online/2017/07/17/report-opioid-pain-sales-hit-18-4b-u-s-2020/#more-31534.

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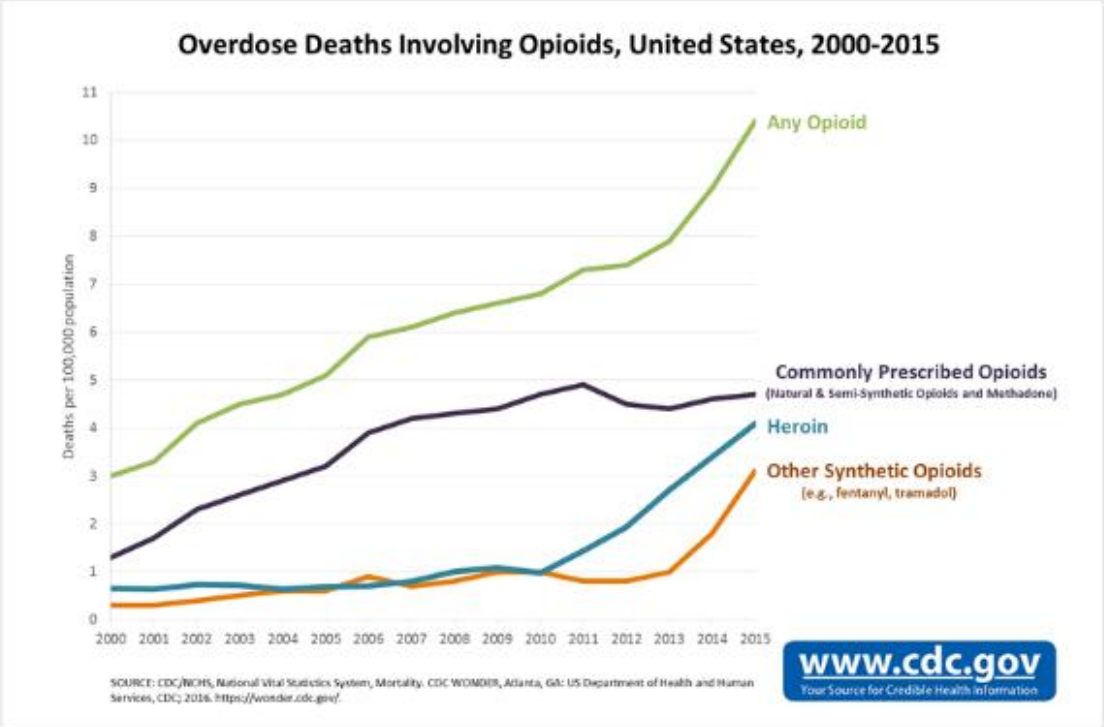
deaths (which include prescription opioids as well as heroin) have risen steadily every year, from approximately 8,048 in 1999, to 20,422 in 2009, to 33,091 in 2015. In 2016, that toll climbed to 42,249.[5]

12. To put these numbers in perspective: in 1970, when a heroin epidemic swept the U.S., there were fewer than 3,000 heroin overdose deaths. And in 1988, around the height of the crack epidemic, there were fewer than 5,000 crack overdose deaths recorded. In 2005, at its peak, methamphetamine was involved in approximately 4,500 deaths.

13. As shown in the graph below, the recent surge in opioid-related deaths involves prescription opioids, heroin, and other synthetic opioids. Nearly half of all opioid overdose deaths involve a prescription opioid like those manufactured by Defendants,[6] and the increase in



[5] *Overdose Death Rates*, NIH Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (revised Sept. 2017); *Drug Overdose Death Data*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last updated December 19, 2017).

[6] *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017).

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overdoses from non-prescription opioids is directly attributable to Defendants' success in expanding the market for opioids of any kind.

14. Just as it has nationally, the opioid epidemic in Washington State, and in Skagit County in particular, has exacted a grim toll. According to the Centers for Disease Control and Prevention ("CDC"), Washington is the only Western state that saw a statistically significant increase in drug overdose death rates between 2014 and 2015.[7] In Skagit County, the rate of opioid-related deaths is higher than the state average, with 11.2 deaths per 100,000 residents compared to a state average of 9.6, between 2012 and 2016.[8] During those four years, sixty-six individuals died in Skagit County from opioid-related overdoses.[9] The high overdose rate corresponds to an alarmingly high opioid prescription rate: more than one quarter of the entire Skagit County population was prescribed an opioid in 2014.[10]

15. Beyond the human cost, the CDC recently estimated that the total economic burden of prescription opioid abuse costs the United States $78.5 billion per year, which includes increased costs for health care and addiction treatment, increased strains on human services and criminal justice systems, and substantial losses in workforce productivity.[11]

16. But even these estimates are conservative. The Council of Economic Advisers—the primary advisor to the Executive Office of the President—recently issued a report estimating that "in 2015, the economic cost of the opioid crisis was $504.0 billion, or 2.8% of GDP that year. This is over six times larger than the most recently estimated economic cost of the

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[7] *Overdose deaths double those from car crashes in Washington*, Q13 Fox (June 16, 2017, 4:53pm), http://q13fox.com/2017/06/16/overdose-deaths-nearly-double-seattle-snohomish-everett-marysville-tacoma/.

[8] *Opioid-related Deaths in Washington State, 2006-2016*, Washington State Department of Health (May 2017) https://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf.

[9] *Id.*

[10] *See Population and Total Controlled Substances Prescriptions, Skagit County, CY 2014*, Washington State Department of Health (May 2017) https://www.doh.wa.gov/Portals/1/Documents/2600/PMPcountyProfiles/630-126-SkagitCountyProfile2014.pdf.

[11] *CDC Foundation's New Business Pulse Focuses on Opioid Overdose Epidemic*, Ctrs. for Disease Control and Prevention (Mar. 15, 2017), https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html.

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epidemic."[12] Whatever the final tally, there is no doubt that this crisis has had a profound economic impact.

17. Defendants orchestrated this crisis. Despite knowing about the true hazards of their products, Defendants misleadingly advertised their opioids as safe and effective for treating chronic pain and pushed hundreds of millions of pills into the marketplace for consumption. Through their sophisticated and well-orchestrated campaign, Defendants touted the purported benefits of opioids to treat pain and downplayed the risks of addiction. Moreover, even as the deadly toll of prescription opioid use became apparent to Defendants in years following OxyContin's launch, Defendants persisted in aggressively selling and distributing prescription opioids, while evading their monitoring and reporting obligations, so that massive quantities of addictive opioids continued to pour into Skagit County and other communities around the United States.

18. Defendants consistently, deliberately, and recklessly made and continue to make false and misleading statements regarding, among other things, the low risk of addiction to opioids, opioids' efficacy for chronic pain and ability to improve patients' quality of life with long-term use, the lack of risk associated with higher dosages of opioids, the need to prescribe more opioids to treat withdrawal symptoms, and that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe opioids.

19. Because of Defendants' misconduct, Skagit County, the Cities of Mount Vernon, Sedro-Woolley, and Burlington, and the La Conner and Mount Vernon School Districts are experiencing a severe public health crisis and has suffered significant economic damages, including but not limited to increased costs related to public health, opioid-related crimes and emergencies, health care, criminal justice, and public safety. Plaintiffs have incurred substantial costs in responding to the crisis and will continue to do so in the future.

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[12] *The Underestimated Cost of the Opioid Crisis*, The Council of Econ. Advisers (Nov. 2017), https://static.politico.com/1d/33/4822776641cfbac67f9bc7dbd9c8/the-underestimated-cost-of-the-opioid-crisis-embargoed.pdf.

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20. Accordingly, Plaintiffs bring this action to hold Defendants liable for their misrepresentations regarding the benefits and risks of opioids, as well as for their failure to monitor, detect, investigate, and report suspicious orders of prescription opioids. This conduct (i) violates the Washington Consumer Protection Act, RCW 19.86 *et seq*., (ii) constitutes a public nuisance under Washington law, (iii) constitutes negligence and gross negligence under Washington law, (iv) has unjustly enriched Defendants, and (v) violates the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq*.

II. PARTIES

Plaintiffs

21. Plaintiff Skagit County ("Skagit County" or "County") is a Washington County organized and existing under the laws of the State of Washington, RCW 36.01 *et seq*. There are approximately 123,000 residents of Skagit County.

22. Plaintiff City of Mount Vernon ("Mount Vernon") is a city located in Skagit County, Washington. Mount Vernon is a code city pursuant to RCW 35A *et seq*. The population of Mount Vernon is approximately 34,590.

23. Plaintiff City of Sedro-Woolley ("Sedro-Woolley") is a city located in Skagit County, Washington. Sedro-Woolley is a code city pursuant to RCW 35A *et seq*. The population of Sedro-Woolley is approximately 11,476.

24. Plaintiff City of Burlington ("Burlington") is a city located in Skagit County, Washington. Burlington is a code city pursuant to RCW 35A *et seq*. The population of Burlington is approximately 8,768. Collectively, Mount Vernon, Sedro-Woolley, and Burlington are referred to herein as the "Cities."

25. Plaintiff La Conner School District is a school district located in Skagit County, Washington. La Conner School District employs over 100 people and serves over 600 students in preschool through twelfth grade. La Conner School District has a preschool, elementary school, and high school.

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26. Plaintiff Mount Vernon School District is a school district located in Skagit County, Washington. Mount Vernon School District employs almost 900 people and serves over 6,200 students in kindergarten through twelfth grade. Mount Vernon School District has six elementary schools, two middle schools, one high school, and one home school parent partnership.

27. Collectively, La Conner School District and Mount Vernon School District are referred to herein as the "School Districts."

Purdue

28. Defendant Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Defendant The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. Collectively, these entities are referred to as "Purdue."

29. Each Purdue entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

30. Purdue manufactures, promotes, sells, markets, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including in Skagit County.

31. Purdue generates substantial sales revenue from its opioids. For example, OxyContin is Purdue's best-selling opioid, and since 2009, Purdue has generated between $2 and $3 billion annually in sales of OxyContin alone.

Endo

32. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Endo Health Solutions Inc. Both are Delaware corporations with their principal place of business in Malvern, Pennsylvania. Collectively, these entities are referred to as "Endo."

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33. Each Endo entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

34. Endo manufactures, promotes, sells, markets, and distributes opioids such as Percocet, Opana, and Opana ER in the United States, including in Skagit County.

35. Endo generates substantial sales from its opioids. For example, opioids accounted for more than $400 million of Endo's overall revenues of $3 billion in 2012, and Opana ER generated more than $1 billion in revenue for Endo in 2010 and 2013.

Janssen and Johnson & Johnson

36. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Collectively, these entities are referred to as "Janssen."

37. Both entities above acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

38. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc., and corresponds with the FDA regarding the drugs manufactured by Janssen Pharmaceuticals, Inc. Johnson & Johnson also paid prescribers to speak about opioids manufactured by Janssen Pharmaceuticals, Inc. In short, Johnson & Johnson controls the sale and development of the drugs manufactured by Janssen Pharmaceuticals, Inc.

39. Janssen manufactures, promotes, sells, markets, and distributes opioids such as Duragesic, Nucynta, and Nucynta ER in the United States, including in Skagit County. Janssen stopped manufacturing Nucynta and Nucynta ER in 2015.

40. Janssen generates substantial sales revenue from its opioids. For example, Duragesic accounted for more than $1 billion in sales in 2009, and Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

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Cephalon and Teva

41. Defendant Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation which is registered to do business in Ohio and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

42. Cephalon manufactures, promotes, sells, and distributes opioids, including Actiq and Fentora, in the United States.

43. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which are distributed with Cephalon opioids, disclose that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

44. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[13] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012—the year following the Cephalon acquisition in October 2011—attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including sales of Fentora.[14] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53%

[13] Actiq, http://www.actiq.com/ (last visited May 22, 2018).

[14] *Teva Pharm. Indus. Ltd. Form 20-F*, U.S. Sec. and Exchange Commission (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

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of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva Ltd. would conduct those companies' business in the United States itself.

45. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Collectively, these entities are referred to as "Cephalon."

Allergan, Actavis, and Watson

46. Defendant Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013.

47. Defendant Actavis, Inc. was acquired by Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013.

48. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

49. Defendant Actavis Pharma, Inc. is registered to do business with the Ohio Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

50. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

51. Each of these defendants and entities is owned by Defendant Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Defendant Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis/Watson products ultimately inure to its benefit. Collectively, these defendants and entities are referred to as "Actavis."

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52. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco and generic versions of Kadian, Duragesic, and Opana in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

Mallinckrodt

53. Mallinckrodt plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in Washington. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt plc. Mallinckrodt plc and Mallinckrodt, LLC are referred to as "Mallinckrodt."

54. Mallinckrodt manufactures, markets, and sells drugs in the United States. As of 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the largest manufacturers of oxycodone in the U.S.

55. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths.

56. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

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57. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

58. In 2017, Mallinckrodt agreed to settle for $35 million the Department of Justice's allegations regarding excessive sales of oxycodone in Florida. The Department of Justice alleged that even though Mallinckrodt knew that its oxycodone was being diverted to illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify the DEA of the suspicious orders in violation of its obligations as a registrant under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA").

59. Defendants Purdue, Endo, Janssen, Cephalon, Actavis, and Mallinckrodt are collectively referred to as the "Manufacturing Defendants."

AmerisourceBergen

60. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania.

61. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies" with "over $145 billion in annual revenue."

62. AmerisourceBergen is licensed as a "wholesale distributor" to sell prescription and non-prescription drugs in Washington State, including opioids. It operates a warehouse in Kent, Washington.

Cardinal Health

63. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio Corporation with its principal place of business in Dublin, Ohio.

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64. According to its 2017 Annual Report, Cardinal Health is "a global, integrated healthcare services and products company serving hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide . . . deliver[ing] medical products and pharmaceuticals." In 2017 alone, Cardinal Health generated revenues of nearly $130 billion.

65. Cardinal Health is licensed as a "wholesale distributor" to sell prescription and non-prescription drugs in Washington State, including opioids. It operates a warehouse in Fife, Washington.

McKesson

66. Defendant McKesson Corporation ("McKesson") is a Delaware Corporation with its principal place of business in San Francisco, California.

67. McKesson is the largest pharmaceutical distributor in North America, delivering nearly one-third of all pharmaceuticals used in this region.

68. According to its 2017 Annual Report, McKesson "partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively." Additionally, McKesson's pharmaceutical distribution business operates and serves thousands of customer locations through a network of twenty-seven distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all fifty states and Puerto Rico.

69. For the fiscal year ending March 31, 2017, McKesson generated revenues of $198.5 billion.

70. McKesson is licensed as a "wholesale distributor" to sell prescription and non-prescription drugs in Washington State, including opioids. It operates warehouses in Everett and Auburn, Washington.

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71. Collectively, McKesson, AmerisourceBergen, and Cardinal Health (together "Distributor Defendants") account for approximately 85% of all drug shipments in the United States.

John and Jane Does 1-100, inclusive

72. In addition to the Defendants identified herein, the true names, roles, and/or capacities in the wrongdoing alleged herein of Defendants named John and Jane Does 1 through 100, inclusive, are currently unknown to Plaintiff, and thus, are named as Defendants under fictitious names as permitted by the rules of this Court. Plaintiffs will amend this complaint and identify their true identities and their involvement in the wrongdoing at issue, as well as the specific causes of action asserted against them when they become known.

III. JURISDICTION AND VENUE

73. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. The Court also has federal question subject matter jurisdiction arising out of Plaintiff's RICO claims pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, *et seq*.

74. Venue in this Court is proper under 28 U.S.C. § 1391(b).

IV. FACTUAL ALLEGATIONS

A. Making an Old Drug New Again

1. A history and background of opioids in medicine

75. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids.[15] Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression. In addition, opioids cause sedation and constipation.

[15] At one time, the term "opiate" was used for natural opioids, while "opioid" referred to synthetic substances manufactured to mimic opiates. Now, however, most medical professionals use "opioid" to refer broadly to natural, semi-synthetic, and synthetic opioids. A fourth class of opioids, endogenous opioids (e.g., endorphins), is produced naturally by the human body.

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76. Most of these effects are medically useful in certain situations, but respiratory depression is the primary limiting factor for the use of opioids. While the body develops tolerance to the analgesic and euphoric effects of opioids relatively quickly, this is not true with respect to respiratory depression. At high doses, opioids can and often do arrest respiration altogether. This is why the risk of opioid overdose is so high, and why many of those who overdose simply go to sleep and never wake up.

77. Natural opioids are derived from the opium poppy and have been used since antiquity, going as far back as 3400 B.C. The opium poppy contains various opium alkaloids, three of which are used commercially today: morphine, codeine, and thebaine.

78. A 16th-century European alchemist, Paracelsus, is generally credited with developing a tincture of opium and alcohol called laudanum, but it was a British physician a century later who popularized the use of laudanum in Western medicine. "Sydenham's laudanum" was a simpler tincture than Paracelsus's and was widely adopted as a treatment not only for pain, but for coughs, dysentery, and numerous other ailments. Laudanum contains almost all of the opioid alkaloids and is still available by prescription today.

79. Chemists first isolated the morphine and codeine alkaloids in the early 1800s, and the pharmaceutical company Merck began large-scale production and commercial marketing of morphine in 1827. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. It was upper and middle class white women, however, who comprised the majority of opioid addicts in the late 19th-century United States, using opioid preparations widely available in pain elixirs, cough suppressants, and patent medicines. By 1900, an estimated 300,000 people were addicted to opioids in the United States, [16] and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms.

[16] Nick Miroff, *From Teddy Roosevelt to Trump: How drug companies triggered an opioid crisis a century ago*, Washington Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.

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80. Trying to develop a drug that could deliver opioids' potent pain relief without their addictive properties, chemists continued to isolate and refine opioid alkaloids. Heroin, first synthesized from morphine in 1874, was marketed commercially by the Bayer Pharmaceutical Company beginning in 1898 as a safe alternative to morphine. Heroin's market position as a safe alternative was short-lived, however; Bayer stopped mass-producing heroin in 1913 because of its dangers. German chemists then looked to the alkaloid thebaine, synthesizing oxymorphone and oxycodone from thebaine in 1914 and 1916, respectively, with the hope that the different alkaloid source might provide the benefits of morphine and heroin without the drawbacks.

81. But each opioid was just as addictive as the one before it, and eventually the issue of opioid addiction could not be ignored. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."[17]

82. Concerns over opioid addiction led to national legislation and international agreements regulating narcotics: the International Opium Convention, signed at the Hague in 1912, and, in the U.S., the Harrison Narcotics Tax Act of 1914. Opioids were no longer marketed as cure-alls and instead were relegated to the treatment of acute pain.

83. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids, but these opioids were generally produced in combination with other drugs, with relatively low opioid content. For example, Percodan, produced by Defendant Endo since 1950, is oxycodone and aspirin, and contains just under 5 mg of oxycodone. Percocet, manufactured by Endo since 1971, is the combination of oxycodone and acetaminophen, with dosage strengths delivering between 2.5 mg and 10 mg of oxycodone. Vicodin, a combination of hydrocodone and acetaminophen, was introduced in the U.S. in 1978

[17] *Id.*

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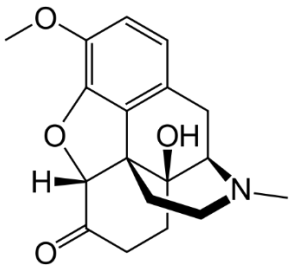
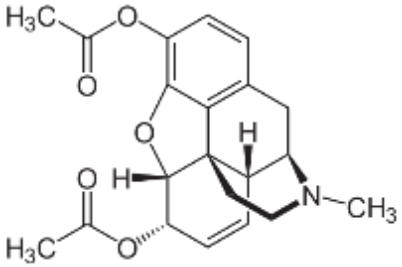
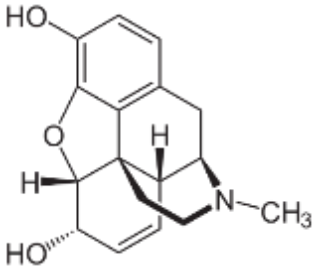
and is sold in strengths of 5 mg, 7.5 mg, and 10 mg of hydrocodone. Defendant Janssen also manufactured a drug with 5 mg of oxycodone and 500 mg of acetaminophen, called Tylox, from 1984 to 2012.

84. In contrast, OxyContin, the product with the dubious honor of the starring role in the opioid epidemic, is pure oxycodone. Purdue initially made it available in the following dosage strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. In other words, the weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times as much as that.

85. Prescription opioids are essentially pharmaceutical heroin; they are synthesized from the same plant, have similar molecular structures, and bind to the same receptors in the human brain. It is no wonder then that there is a straight line between prescription opioid abuse and heroin addiction. Indeed, studies show that over 80% of new heroin addicts between 2008 and 2010 started with prescription opioids.[18]

Oxycodone	Heroin	Morphine
		

86. Medical professionals describe the strength of various opioids in terms of "morphine milligram equivalents" ("MME"). According to the CDC, dosages at or above 50

[18] Jones CM, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010*, 132(1-2) Drug Alcohol Depend. 95-100 (Sept. 1, 2013), https://www.ncbi.nlm.nih.gov/pubmed/23410617.

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MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

87. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.[19]

88. As journalist Barry Meier wrote in his 2003 book *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death*, "In terms of narcotic firepower, OxyContin was a nuclear weapon."[20]

89. Fentanyl, an even more potent and more recent arrival in the opioid tale, is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959 by Dr. Paul Janssen under a patent held by Janssen Pharmaceutica, fentanyl is increasingly prevalent in the market for opioids created by Defendants' promotion, with particularly lethal consequences. In many instances, illicit fentanyl is manufactured to look like oxycodone tablets, in the light blue color and with the "M" stamp of Defendant Mallinckrodt's 30mg oxycodone pills. These lookalike pills have been found around the country, including in Washington State.[21]

2. The Sackler family pioneered the integration of advertising and medicine.

90. Given the history of opioid use in the U.S. and the medical profession's resulting wariness, the commercial success of Defendants' prescription opioids would not have been

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[19] The wide variation in the MME strength of prescription opioids renders misleading any effort to capture "market share" by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

[20] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (Rodale 2003).

[21] *See e.g.*, Sharon Bogan, *Illicit fentanyl found locally in fake opioid pills*, Public Health Insider (Oct. 2, 2017), https://publichealthinsider.com/2017/10/02/illicit-fentanyl-found-locally-in-fake-opioid-pills/; *Mislabeled painkillers "a fatal overdose waiting to happen,"* CBS News (Feb. 29, 2016, 10:46am), https://www.cbsnews.com/news/mislabeled-painkillers-a-fatal-overdose-waiting-to-happen/.

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possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

91. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, surpassing the wealth of storied families like the Rockefellers, the Mellons, and the Busches.[22] Because of Purdue and, in particular, OxyContin, the Sacklers' net worth was $13 billion as of 2016. Today, all nine members of the Purdue board are family members, and all of the company's profits go to Sackler family trusts and entities.[23] Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

92. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called The Purdue Frederick Company in 1952. While all three brothers were accomplished psychiatrists, it was Arthur, the oldest, who directed the Sackler story, treating his brothers more as his protégés than colleagues, putting them both through medical school and essentially dictating their paths. It was Arthur who created the Sackler family's wealth, and it was Arthur who created the pharmaceutical advertising industry as we know it—laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

93. Arthur Sackler was both a psychiatrist and a marketing executive, and, by many accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at Creedmoor State Hospital in New York and the president of an advertising agency called William Douglas McAdams. Arthur pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical

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[22] Alex Morrell, *The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, Forbes (July 1, 2015, 10:17am), https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#382ab3275e02.

[23] David Armstrong, *The man at the center of the secret OxyContin files*, Stat News (May 12, 2016), https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/.

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education courses. He understood intuitively the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.[24]

94. It was Arthur who, in the 1960s, made Valium into the first $100-million drug, so popular it became known as "Mother's Little Helper." His expertise as a psychiatrist was key to his success; as his biography in the Medical Advertising Hall of Fame notes, it "enabled him to position different indications for Roche's Librium and Valium—to distinguish for the physician the complexities of anxiety and psychic tension."[25] When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called "psychic tension"—essentially stress—and pitched Valium as the solution.[26] The campaign, for which Arthur was compensated based on volume of pills sold,[27] was a remarkable success.

95. Arthur's entrepreneurial drive led him to create not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which he distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like Defendants, who utilize it to tailor their sales pitches to individual physicians.

96. Even as he expanded his business dealings, Arthur was adept at hiding his involvement in them. When, during a 1962 Senate hearing about deceptive pharmaceutical

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[24] Meier, *supra* note 20, at 204.

[25] *MAHF Inductees, Arthur M. Sackler*, Med. Advert. Hall of Fame, https://www.mahf.com/mahf-inductees/ (last visited May 22, 2018).

[26] Meier, *supra* note 20, at 202; *One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids.

[27] WBUR On Point interview, *supra* note 26.

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advertising, he was asked about a public relations company called Medical and Science Communications Associates, which distributed marketing from drug companies disguised as news articles, Arthur was able to truthfully testify that he never was an officer for nor had any stock in that company. But the company's sole shareholder was his then-wife. Around the same time, Arthur also successfully evaded an investigative journalist's attempt to link the Sacklers to a company called MD Publications, which had funneled payments from drug companies to an FDA official named Henry Welch, who was forced to resign when the scandal broke.[28] Arthur had set up such an opaque and layered business structure that his connection to MD Publications was only revealed decades later when his heirs were fighting over his estate.

97. Arthur Sackler did not hesitate to manipulate information to his advantage. His legacy is a corporate culture that prioritizes profits over people. In fact, in 2007, federal prosecutors conducting a criminal investigation of Purdue's fraudulent advertising of OxyContin found a "corporate culture that allowed this product to be misbranded with the intent to defraud and mislead."[29] Court documents from the prosecution state that "certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications . . . "[30] Half a century after Arthur Sackler wedded advertising and medicine, Purdue employees were following his playbook, putting product sales over patient safety.

3. Purdue and the development of OxyContin

98. After the Sackler brothers acquired The Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in

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[28] Meier, *supra* note 20, at 210-14.

[29] Naomi Spencer, *OxyContin manufacturer reaches $600 million plea deal over false marketing practices*, World Socialist Web Site (May 19, 2007), http://www.wsws.org/en/articles/2007/05/oxy-m19.html.

[30] Agreed Statement of Facts, *United States. v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

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running Purdue because that would have been a conflict of interest. Raymond Sackler became Purdue's head executive while Mortimer Sackler ran Purdue's UK affiliate.

99. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin. It quickly became Purdue's best seller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond Sackler's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard Sackler had grand ambitions for the company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big."[31] Richard Sackler believed Purdue should develop another use for its "Contin" timed-release system.

100. In 1990, Purdue's VP of clinical research, Robert Kaiko, sent a memo to Richard Sackler and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, the relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxy*codeine*," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it eventually pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.[32]

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[31] Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.

[32] *United States. v. Purdue Frederick Co*., *supra* note 30.

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101. For Purdue and OxyContin to be "*really* big," Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase.[33] As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

102. Despite the fact that there has been little or no change in the amount of pain reported in the U.S. over the last twenty years, Purdue recognized an enormous untapped market for its new drug. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."[34]

103. In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or Defendant Janssen's spending on Duragesic:[35]

[33] Meier, *supra* note 20, at 269.
[34] *Id.* at 156.
[35] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. Gen. Acct. Off. Rep. to Cong. Requesters at 22 (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.

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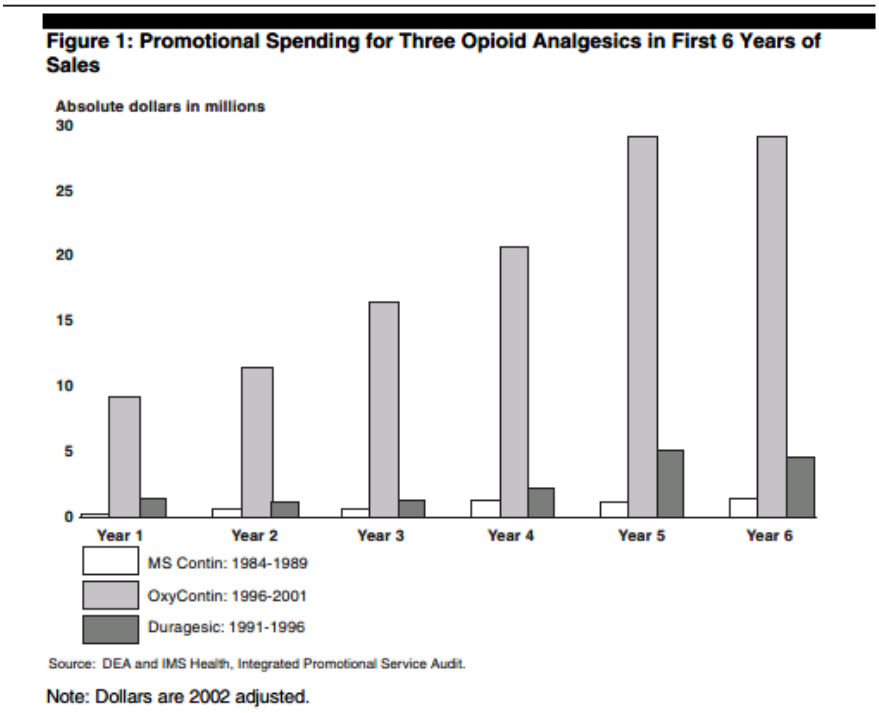

104. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners. Today, one in every five patients who present themselves to physicians' offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receives an opioid prescription.[36]

105. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, while raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy.

[36] Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Ctrs. for Disease Control and Prevention (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm [hereinafter 2016 CDC Guideline].

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The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

106. One might imagine that Richard Sackler's ambitions have been realized. But in the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits. Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

107. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

> We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . . .
>
> Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .
>
> In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.[37]

[37] Letter from Cong. of the U.S., to Dr. Margaret Chan, Dir.-Gen., World Health Org. (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf.

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108. Purdue's pivot to untapped markets, after extracting substantial profits from communities like Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, and Burlington and leaving them to address the resulting damage, underscores that its actions have been knowing, intentional, and motivated by profits throughout this entire tragic story.

B. The Booming Business of Addiction

1. Other Manufacturing Defendants leapt at the opioid opportunity.

109. Purdue created a market in which the prescription of powerful opioids for a range of common aches and pains was not only acceptable but encouraged—but it was not alone. Defendants Endo, Janssen, Cephalon, and Actavis, each of which already produced and sold prescription opioids, positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin while misrepresenting the safety and efficacy of their products.

110. Endo, which for decades had sold Percocet and Percodan, both containing relatively low doses of oxycodone, moved quickly to develop a generic version of extended-release oxycodone to compete with OxyContin, receiving tentative FDA approval for its generic version in 2002. As Endo stated in its 2003 Form 10-K, it was the first to file an application with the FDA for bioequivalent versions of the 10, 20, and 40 mg strengths of OxyContin, which potentially entitled it to 180 days of generic marketing exclusivity—"a significant advantage."[38] Purdue responded by suing Endo for patent infringement, litigating its claims through a full trial and a Federal Circuit appeal—unsuccessfully. As the trial court found, and the appellate court affirmed, Purdue obtained the oxycodone patents it was fighting to enforce through "inequitable conduct"—namely, suggesting that its patent applications were supported by clinical data when in fact they were based on an employee's "insight and not scientific proof."[39] Endo began selling its generic extended-release oxycodone in 2005.

[38] *Endo Pharm. Holdings, Inc. Form 10-K,* U.S. Sec. and Exchange Comm'n, at 4 (Mar. 15, 2004), http://media.corporate-ir.net/media_files/irol/12/123046/reports/10K_123103.pdf.

[39] *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1131 (Fed. Cir. 2006).

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111. At the same time as Endo was battling Purdue over generic OxyContin—and as the U.S. was battling increasingly widespread opioid abuse—Endo was working on getting another branded prescription opioid on the market. In 2002, Endo submitted applications to the FDA for both immediate-release and extended-release tablets of oxymorphone, branded as Opana and Opana ER.

112. Like oxycodone, oxymorphone is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan, in injectable, suppository, and oral tablet forms. But the oral tablets proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin, and even had its moment in the limelight as the focus of the movie Drugstore Cowboy. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict Lifestyle," Numorphan was extremely popular among addicts for its quick and sustained effect.[40] Endo withdrew oral Numorphan from the market in 1979, reportedly for "commercial reasons."[41]

113. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name and a potent extended-release formulation.

114. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone, an opioid antagonist used to counter the effects of an overdose. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not

[40] John Fauber and Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), https://www.medpagetoday.com/psychiatry/addictions/51448.

[41] *Id.*

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respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

115. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[42] On July 6, 2017, Endo agreed to withdraw Opana ER from the market.[43]

116. Janssen, which already marketed the Duragesic (fentanyl) patch, developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011.

117. Cephalon also manufactures Actiq, a fentanyl lozenge, and Fentora, a fentanyl tablet. As noted above, fentanyl is an extremely powerful synthetic opioid. According to the DEA, as little as two milligrams is a lethal dosage for most people. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[44] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[45]

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[42] Press Release, U.S. Food & Drug Administration, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[43] *Endo pulls opioid as U.S. seeks to tackle abuse epidemic*, Reuters (July 6, 2017, 9:59am), https://www.reuters.com/article/us-endo-intl-opana-idUSKBN19R2II.

[44] *Prescribing Information, ACTIQ®*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf (last visited May 22, 2018).

[45] *Prescribing Information, FENTORA®*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf (last visited May 22, 2018).

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118. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

119. Actavis acquired the rights to Kadian, extended-release morphine, in 2008, and began marketing Kadian in 2009. Actavis's opioid products also include Norco, a brand-name hydrocodone and acetaminophen pill, first approved in 1997. But Actavis, primarily a generic drugmaker, pursued opioid profits through generics, selling generic versions of OxyContin, Opana, and Duragesic. In 2013, it settled a patent lawsuit with Purdue over its generic version of "abuse-deterrent" OxyContin, striking a deal that would allow it to market its abuse-deterrent oxycodone formulation beginning in 2014. Actavis anticipated over $100 million in gross profit from generic OxyContin sales in 2014 and 2015.

120. Mallinckrodt's generic oxycodone achieved enough market saturation to have its own street name, "M's," based on its imprint on the pills. As noted above, Mallinckrodt was the subject of a federal investigation based on diversion of its oxycodone in Florida, where 500 million of its pills were shipped between 2008 and 2012. Federal prosecutors alleged that 43,991 orders from distributors and retailers were excessive enough be considered suspicious and should have been reported to the DEA.

121. Mallinckrodt also pursued a share of the branded opioid market. In 2009, Mallinckrodt acquired the U.S. rights to Exalgo, a potent extended-release hydromorphone tablet, and began marketing it in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014. In anticipation of Xartemis XR's

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approval, Mallinckrodt hired approximately 200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[46]

122. All told, the Manufacturing Defendants have reaped enormous profits from the addiction crisis they spawned. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013. Janssen earned more than $1 billion in sales of Duragesic in 2009, and Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

2. Distributor Defendants knowingly supplied dangerous quantities of opioids while advocating for limited oversight and enforcement.

123. The Distributor Defendants track and keep a variety of information about the pharmacies and other entities to which they sell pharmaceuticals. For example, the Distributor Defendants use "know your customer" questionnaires that track the number and types of pills their customers sell, absolute and relative amounts of controlled substances they sell, whether the customer purchases from other distributors, and types of medical providers in the areas, among other information.

124. These questionnaires and other sources of information available to the Distributor Defendants provide ample data to put the Distributor Defendants on notice of suspicious orders, pharmacies, and doctors.

125. Nevertheless, the Distributor Defendants refused or failed to identify, investigate, or report suspicious orders of opioids to the DEA. Even when the Distributor Defendants had actual knowledge that they were distributing opioids to drug diversion rings, they refused or failed to report these sales to the DEA.

126. By not reporting suspicious opioid orders or known diversions of prescription opioids, not only were the Defendants able to continue to sell opioids to questionable customers,

[46] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Bus. Journal (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/.

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Defendants ensured that the DEA had no basis for decreasing or refusing to increase production quotas for prescription opioids.

127. The Distributor Defendants collaborated with each other and with the Manufacturing Defendants to maintain distribution of excessive amounts of opioids. One example of this collaboration came to light through Defendants' work in support of legislation called the Ensuring Patient Access and Effective Drug Enforcement (EPAEDE) Act, which was signed into law in 2016 and limited the DEA's ability to stop the flow of opioids. Prior to this law, the DEA could use an "immediate suspension order" to halt suspicious shipments of pills that posed an "imminent" threat to the public. The EPAEDE Act changed the required showing to an "immediate" threat—an impossible standard given the fact that the drugs may sit on a shelf for a few days after shipment. The law effectively neutralized the DEA's ability to bring enforcement actions against distributors.

128. The legislation was drafted by a former DEA lawyer, D. Linden Barber, who is now a senior vice president at Defendant Cardinal Health. Prior to leaving the DEA, Barber had worked with Joseph Rannazzisi, then the chief of the DEA's Office of Diversion Control, to plan the DEA's fight against the diversion of prescription drugs. So when Barber began working for Cardinal Health, he knew just how to neutralize the effectiveness of the DEA's enforcement actions. Barber and other promoters of the EPAEDE Act portrayed the legislation as maintaining patient access to medication critical for pain relief. In a 2014 hearing on the bill, Barber testified about the "unintended consequences in the supply chain" of the DEA's enforcement actions. But by that time, communities across the United States, including Plaintiffs Skagit County and the Cities of Mount Vernon, Sedro-Woolley, and Burlington, were grappling with the "unintended consequences" of Defendants' reckless promotion and distribution of narcotics.

129. Despite egregious examples of drug diversion from around the country, the promoters of the EPAEDE Act were successful in characterizing the bill as supporting patients' rights. One of the groups supporting this legislation was the Alliance for Patient Access, a "front

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group" as discussed further below, which purports to advocate for patients' rights to have access to medicines, and whose 2017 list of "associate members and financial supporters" included Defendants Purdue, Endo, Johnson & Johnson, Actavis, Mallinckrodt, and Cephalon. In a 2013 "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse," the Alliance for Patient Access asserted multiple "unintended consequences" of regulating pain medication, including a decline in prescriptions as physicians feel burdened by regulations and stigmatized.[47]

130. The Distributor Defendants are also part of the activities of the Alliance for Patient Access, although their involvement is hidden. One example of their involvement was revealed by the metadata of an electronic document: the letter from the Alliance for Patient Access in support of the EPAEDE Act. That document was created by Kristen Freitas, a registered lobbyist and the vice president for federal government affairs of the Healthcare Distributors Alliance (HDA)—the trade group that represents Defendants McKesson, Cardinal Health, and AmerisourceBergen.

131. Upon information and belief, the collaboration on the EPAEDE Act is just one example of how the Manufacturing Defendants and the Distributor Defendants, through third-party "front groups" like the Alliance for Patient Access and trade organizations like HDA, worked together behind the scenes to ensure that the flow of dangerous narcotics into communities across the country would not be restricted, and Defendants collaborated in other ways that remain hidden from public view.

132. The Distributor Defendants have been the subject of numerous enforcement actions by the DEA. In 2008, for example, McKesson was fined $13.3 million and agreed to strengthen its controls by implementing a three-tiered system that would flag buyers who exceeded monthly thresholds for opioids. As the opioid crisis deepened, the DEA's Office of

[47] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Inst. for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

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Diversion Control, led by Rannazzisi, stepped up enforcement, filing fifty-two immediate suspension orders against suppliers and pill mills in 2010 alone. Defendant Cardinal Health was fined $34 million by the DEA in 2013 for failing to report suspicious orders.

133. The Distributor Defendants were not simply passive transporters of opioids. They intentionally failed to report suspicious orders and actively pushed back against efforts to enforce the law and restrict the flow of opioids into communities like Skagit County, Mount Vernon, Sedro-Woolley, and Burlington.

3. Pill mills and overprescribing doctors also placed their financial interests ahead of their patients' interests.

134. Prescription opioid manufacturers and distributors were not the only ones to recognize an economic opportunity. Around the country, including in Skagit County and the Cities of Mount Vernon, Sedro-Woolley, and Burlington, certain doctors or pain clinics ended up doing brisk business dispensing opioid prescriptions. As Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, observed, this business model meant doctors would "have a practice of patients who'll never miss an appointment and who pay in cash."[48]

135. Moreover, the Manufacturing Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions. Eventually, the DEA's diversion unit raided the clinic, and prosecutors filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,

[48] Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* 314 (Bloomsbury Press 2015).

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Wilson was Purdue's top-ranked sales representative.[49] In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[50]

136. Another pill mill, this one in Los Angeles, supplied OxyContin to a drug dealer in Everett, Washington. Purdue was alerted to the existence of this pill mill by one of its regional sales managers, who in 2009 reported to her supervisors that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]" She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report." This clinic was the source of 1.1 million pills trafficked to Everett, which is a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.[51] Similarly, Purdue received repeated reports in 2008 from a sales representative who visited a family practice doctor in Bothell, Washington; the sales representative informed Purdue that many of this doctor's patients were men in their twenties who did not appear to be in pain, who sported diamond studs and $350 sneakers, and who always paid for their 80 mg OxyContin prescriptions in cash. Despite being repeatedly alerted to the doctor's conduct, Purdue did not take any action to report it until three years later.

137. Whenever examples of opioid diversion and abuse have drawn media attention, the Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions

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[49] Meier, *supra* note 20, at 298-300.

[50] *Id.*

[51] Harriet Ryan, Scott Glover, and Lisa Girion, *How black-market OxyContin spurred a town's descent into crime, addiction and heartbreak*, Los Angeles Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-everett/; Harriet Ryan, Lisa Girion, and Scott Glover, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

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about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the "bad actor" doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[52]

138. But given the closeness with which all Defendants monitored prescribing patterns, including through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Rather, it appears Purdue and other Defendants used the IMS Health data to target pill mills and sell more pills. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

139. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

4. Widespread prescription opioid use broadened the market for heroin and fentanyl.

140. Defendants' scheme achieved a dramatic expansion of the U.S. market for opioids, prescription and non-prescription alike. Heroin and fentanyl use has surged—a foreseeable consequence of Defendants' successful promotion of opioid use coupled with the sheer potency of their products.

[52] Meier, *supra* note 20, at 179.

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141. In his book *Dreamland: The True Tale of America's Opiate Epidemic*, journalist Sam Quinones summarized the easy entrance of black tar heroin in a market primed by prescription opioids:

> His black tar, once it came to an area where OxyContin had already tenderized the terrain, sold not to tapped-out junkies but to younger kids, many from the suburbs, most of whom had money and all of whom were white. Their transition from Oxy to heroin, he saw, was a natural and easy one. Oxy addicts began by sucking on and dissolving the pills' timed-release coating. They were left with 40 or 80 mg of pure oxycodone. At first, addicts crushed the pills and snorted the powder. As their tolerance built, they used more. To get a bigger bang from the pill, they liquefied it and injected it. But their tolerance never stopped climbing. OxyContin sold on the street for a dollar a milligram and addicts very quickly were using well over 100 mg a day. As they reached their financial limits, many switched to heroin, since they were already shooting up Oxy and had lost any fear of the needle.[53]

142. In a study examining the relationship between the abuse of prescription opioids and heroin, researchers found that 75% of those who began their opioid abuse in the 2000s reported that their first opioid was a prescription drug.[54] As the graph below illustrates, prescription opioids replaced heroin as the first opioid of abuse beginning in the 1990s.

[53] Quinones, *supra* note 48, at 165-66.

[54] Theodore J. Cicero, PhD, Matthew S. Ellis, MPE, Hilary L. Surratt, PhD, *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71(7) JAMA Psychiatry 821-826 (2014), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575.

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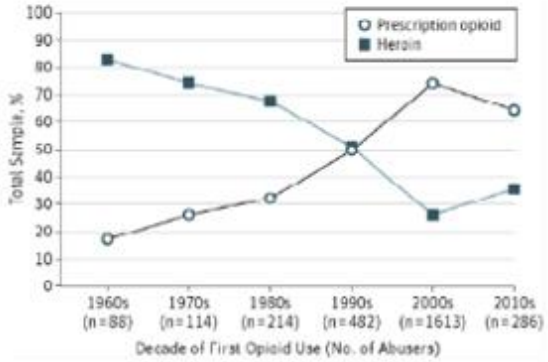

Figure Legend:

Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of AbuseData are plotted as a function of the decade in which respondents initiated their opioid abuse.

143. The researchers also found that nearly half of the respondents who indicated that their primary drug was heroin actually preferred prescription opioids, because the prescription drugs were legal, and perceived as "safer and cleaner." But, heroin's lower price point is a distinct advantage. While an 80 mg OxyContin might cost $80 on the street, the same high can be had from $20 worth of heroin.

144. As noted above, there is little difference between the chemical structures of heroin and prescription opioids. Between 2005 and 2009, Mexican heroin production increased by over 600%. And between 2010 and 2014, the amount of heroin seized at the U.S.-Mexico border more than doubled.

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145. From 2002 to 2016, fatal overdoses related to heroin in the U.S. increased by **533%**—from 2,089 deaths in 2002 to 13,219 deaths in 2016.[55]

146. Along with heroin use, fentanyl use is on the rise, as a result of America's expanded appetite for opioids. But fentanyl, as noted above, is fifty times more potent than heroin, and overdosing is all too easy. Fentanyl is expected to cause over 20,000 overdoses in 2017.[56]

147. As Dr. Caleb Banta-Green, senior research scientist at the University of Washington's Alcohol and Drug Abuse Institute, told The Seattle Times in August 2017, "The bottom line is opioid addiction is the overall driver of deaths. People will use whatever opioid they can get. It's just that which one they're buying is changing a bit."[57]

C. The Manufacturing Defendants Promoted Prescription Opioids Through Several Channels.

148. Despite knowing the devastating consequences of widespread opioid use, the Manufacturing Defendants engaged in a sophisticated and multi-pronged promotional campaign designed to achieve just that. By implementing the strategies pioneered by Arthur Sackler, these Defendants were able to achieve the fundamental shift in the perception of opioids that was key to making them blockbuster drugs.

149. The Manufacturing Defendants disseminated their deceptive statements about opioids through several channels.[58] First, these Defendants aggressively and persistently pushed opioids through sales representatives. Second, these Defendants funded third-party organizations that appeared to be neutral but which served as additional marketing departments for drug companies. Third, these Defendants utilized prominent physicians as paid spokespeople—"Key

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[55] Niall McCarthy, *U.S. Heroin Deaths Have Increased 533% Since 2002*, Forbes (Sept. 11, 2017, 8:26am), https://www.forbes.com/sites/niallmccarthy/2017/09/11/u-s-heroin-deaths-have-increased-533-since-2002-infographic/#13ab9a531abc.

[56] *Id.*

[57] *Opioids: The Leading Cause of Drug Deaths in Seattle Area*, U. of Wash. Sch. of Pub. Health (Aug. 25, 2017), http://sph.washington.edu/news/article.asp?content_ID=8595.

[58] The specific misrepresentations and omissions are discussed below in Section D.

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Opinion Leaders"—to take advantage of doctors' respect for and reliance on the recommendations of their peers. Finally, these Defendants also used print and online advertising, including unbranded advertising, which is not reviewed by the FDA.

150. The Manufacturing Defendants spent substantial sums and resources in making these communications. For example, Purdue spent more than $200 million marketing OxyContin in 2001 alone.[59]

1. The Manufacturing Defendants aggressively deployed sales representatives to push their products.

151. The Manufacturing Defendants communicated to prescribers directly in the form of in-person visits and communications from sales representatives.

152. The Manufacturing Defendants' tactics through their sales representatives—also known as "detailers"—were particularly aggressive. In 2014, Manufacturing Defendants collectively spent well over $100 million on detailing branded opioids to doctors.

153. Each sales representative has a specific sales territory and is responsible for developing a list of about 105 to 140 physicians to call on who already prescribe opioids or who are candidates for prescribing opioids.

154. When Purdue launched OxyContin in 1996, its 300-plus sales force had a total physician call list of approximately 33,400 to 44,500. By 2000, nearly 700 representatives had a total call list of approximately 70,500 to 94,000 physicians. Each sales representative was expected to make about thirty-five physician visits per week and typically called on each physician every three to four weeks, while each hospital sales representative was expected to make about fifty physician visits per week and call on each facility every four weeks.[60]

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[59] *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of Paul Goldenheim, Vice President for Research, Purdue Pharma), https://www.gpo.gov/fdsys/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm.

[60] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 35, at 20.

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155. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[61] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."[62]

156. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist that the most common objection he heard about prescribing OxyContin was that "it's just too addictive."[63] In order to overcome that objection and hit their "target," May and other sales representatives were taught to say, "The delivery system is believed to reduce the abuse liability of the drug."[64] May repeated that line to doctors even though he "found out pretty fast that it wasn't true."[65] He and his coworkers learned quickly that people were figuring out how to remove the time-releasing coating, but they continued making this misrepresentation until Purdue was forced to remove it from the drug's label.

157. Purdue trained its sales representatives to misrepresent the addiction risk in other ways. May explained that he and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours. Similarly, former Purdue sales

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[61] Meier, *supra* note 20, at 102.

[62] *Id.*

[63] David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

[64] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain; see also Meier, *supra* note 20, at 102 ("Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of the drug.").

[65] Keefe, *supra* note 64.

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manager William Gergely told a Florida state investigator in 2002 that sales representatives were instructed to say that OxyContin was "virtually non-addicting" and "non-habit-forming."[66]

158. As Shelby Sherman, a Purdue sales representative from 1974 to 1998, told a reporter regarding OxyContin promotion, "It was sell, sell, sell. We were directed to lie. Why mince words about it?"[67]

159. The Manufacturing Defendants utilized lucrative bonus systems to encourage their sales representatives to stick to the script and increase opioid sales in their territories. Purdue paid $40 million in sales incentive bonuses to its sales representatives in 2001 alone, with annual bonuses ranging from $15,000 to nearly $240,000.[68] The training memo described above, in keeping with a Wizard of Oz theme, reminded sales representatives: "A pot of gold awaits you 'Over the Rainbow'!"[69]

160. As noted above, these Defendants have also spent substantial sums to purchase, manipulate, and analyze prescription data available from IMS Health, which allows them to track initial prescribing and refill practices by individual doctors, and in turn to customize their communications with each doctor. The Manufacturing Defendants' use of this marketing data was a cornerstone of their marketing plan,[70] and continues to this day.

161. The Manufacturing Defendants also aggressively pursued family doctors and primary care physicians perceived to be susceptible to their marketing campaigns. The Manufacturing Defendants knew that these doctors relied on information provided by pharmaceutical companies when prescribing opioids, and that, as general practice doctors seeing

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[66] Fred Schulte and Nancy McVicar, *Oxycontin Was Touted As Virtually Nonaddictive, Newly Released State Records Show*, Sun Sentinel (Mar. 6, 2003), http://articles.sun-sentinel.com/2003-03-06/news/0303051301_1_purdue-pharma-oxycontin-william-gergely.

[67] Glazek, *supra* note 31.

[68] Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J Public Health 221-27 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

[69] Meier, *supra* note 20, at 103.

[70] Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 68.

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a high volume of patients on a daily basis, they would be less likely to scrutinize the companies' claims.

162. Furthermore, the Manufacturing Defendants knew or should have known the doctors they targeted were often poorly equipped to treat or manage pain comprehensively, as they often had limited resources or time to address behavioral or cognitive aspects of pain treatment or to conduct the necessary research themselves to determine whether opioids were as beneficial as these Defendants claimed. In fact, the majority of doctors and dentists who prescribe opioids are not pain specialists. For example, a 2014 study conducted by pharmacy benefit manager Express Scripts reviewing narcotic prescription data from 2011 to 2012 concluded that of the more than 500,000 prescribers of opioids during that time period, *only 385* were identified as pain specialists.[71]

163. When the Manufacturing Defendants presented these doctors with sophisticated marketing material and apparently scientific articles that touted opioids' ability to easily and safely treat pain, many of these doctors began to view opioids as an efficient and effective way to treat their patients.

164. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative in Florida wrote about working for a particularly driven regional manager named Chris Sposato and described how Sposato would drill the sales team on their upselling tactics:

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."
>
> The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Miami

[71] *A Nation in Pain*, Express Scripts (Dec. 9, 2014), http://lab.express-scripts.com/lab/publications/a-nation-in-pain.

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> District reps have told me that on work sessions with [Sposato] they would sit in the car and role play for as long as it took until [Sposato] was convinced the rep was delivering the message with perfection.

165. The Manufacturing Defendants used not only incentives but competitive pressure to push sales representatives into increasingly aggressive promotion. One Purdue sales representative recalled the following scene: "I remember sitting at a round table with others from my district in a regional meeting while everyone would stand up and state the highest dose that they had suckered a doctor to prescribe. The entire region!!"

166. Sales representatives also quickly learned that the prescription opioids they were promoting were dangerous. For example, May had only been at Purdue for two months when he found out that a doctor he was calling on had just lost a family member to an OxyContin overdose.[72] And as another sales representative wrote on a public forum:

> Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

167. These sales representatives targeted their efforts at local doctors in Washington State, such as, for example, Dr. Frank Li, the former medical director of several pain clinics (including one in Everett, Washington, near the Tulalip Reservation) who eventually had his medical license suspended for improperly prescribing opioids. Indeed, during detailers' frequent visits to Dr. Li, they often noted circumstances that should have led them to discontinue sales calls and report Dr. Li and his staff to the appropriate authorities. Instead, they continued to target him for detailing visits that incited him to prescribe even more opioids, with disastrous consequences for public health.

[72] Remnick, *supra* note 63.

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168. In addition, detailers told providers at Dr. Li's clinic that the Washington State opioid prescription guidelines were wrong and overly conservative, including those related to calculating the relative strength of different brands of opioids. These detailers often urged Dr. Li's staff to give patients more opioids, and particular brands of opioids, even when this was incorrect or conflicted with Washington State guidelines or other medical information.

169. Purdue's sales call notes also repeatedly reference how busy Dr. Li and his staff were—which, combined with the exceptionally high number of opioid prescriptions written by Dr. Li, should have been another red flag that OxyContin and other opioids were likely being abused.

170. The Manufacturing Defendants' sales representatives also provided health care providers with pamphlets, visual aids, and other marketing materials designed to increase the rate of opioids prescribed to patients. These sales representatives knew the doctors they visited relied on the information they provided, and that the doctors had minimal time or resources to investigate the materials' veracity independently.

171. Sales representatives were also given bonuses when doctors whom they had detailed wrote prescriptions for their company's drug. Because of this incentive system, sales representatives stood to gain significant bonuses if they had a pill mill in their sales region.[73] Sales representatives could be sure that doctors and nurses at pill mills would be particularly receptive to their messages and incentives, and receive "credit" for the many prescriptions these pill mills wrote.

172. The Manufacturing Defendants applied this combination of intense competitive pressure and lucrative financial incentives because they knew that sales representatives, with their frequent in-person visits with prescribers, were incredibly effective. In fact, manufacturers'

[73] Indeed, Defendants often helped their sales representatives find and target such pill mills. As recently as 2016, Purdue commissioned a marketing study to help target Washington prescribers and spread its deceptive message regarding opioids, and on information and belief, utilized its sale representatives to carry out these strategies.

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internal documents reveal that they considered sales representatives their "most valuable resource."

2. The Manufacturing Defendants bankrolled seemingly independent "front groups" to promote opioid use and fight restrictions on opioids.

173. The Manufacturing Defendants funded, controlled, and operated third-party organizations that communicated to doctors, patients, and the public the benefits of opioids to treat chronic pain. These organizations—also known as "front groups"—appeared independent and unbiased. But in fact, they were but additional paid mouthpieces for the drug manufacturers. These front groups published prescribing guidelines and other materials that promoted opioid treatment as a way to address patients' chronic pain. The front groups targeted doctors, patients, and lawmakers, all in coordinated efforts to promote opioid prescriptions.

174. The Manufacturing Defendants spent significant financial resources contributing to and working with these various front groups to increase the number of opioid prescriptions written.

175. The most prominent front group utilized by the Manufacturing Defendants was the **American Pain Foundation** (APF), which received more than $10 million from opioid drug manufacturers, including Defendants, from 2007 through 2012. For example, Purdue contributed $1.7 million and Endo also contributed substantial sums to the APF.[74]

176. Throughout its existence, APF's operating budget was almost entirely comprised of contributions from prescription opioid manufacturers. For instance, nearly 90% of APF's $5 million annual budget in 2010 came from "donations" from some of the Manufacturing Defendants, and by 2011, APF was entirely dependent on grants from drug manufacturers, including from Purdue and Endo. Not only did Defendants control APF's purse strings, APF's

[74]Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011, 9:15am), https://www.propublica.org/article/the-champion-of-painkillers.

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board of directors was comprised of doctors who were on Defendants' payrolls, either as consultants or speakers at medical events.[75]

177. Although holding itself out as an independent advocacy group promoting patient well-being, APF consistently lobbied against federal and state proposals to limit opioid use.

178. Another prominent front group was the **American Academy of Pain Medicine** (AAPM), which has received over $2.2 million in funding since 2009 from opioid drug manufacturers, including Defendants. Like APF, AAPM presented itself as an independent and non-biased advocacy group representing physicians practicing in the field of pain medicine, but in fact was just another mouthpiece the Manufacturing Defendants used to push opioids on doctors and patients.[76]

179. Both the APF and the AAPM published treatment guidelines and sponsored and hosted medical education programs that touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks. The treatment guidelines the front groups published—many of which are discussed in detail below—were particularly important to Defendants in ensuring widespread acceptance for opioid therapy to treat chronic pain. Defendants realized, just as the CDC has, that such treatment guidelines can "change prescribing practices," because they appear to be unbiased sources of evidence-based information, even when they are in reality marketing materials.

180. For instance, the AAPM, in conjunction with the **American Pain Society** (APS), issued comprehensive guidelines in 2009 titled "Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain – Evidence Review" ("2009 Guidelines"). The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence to support this statement. Unsurprisingly, the Manufacturing

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[75] *Id.*

[76] Tracy Weber and Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14am), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry.

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Defendants have widely referenced and promoted these guidelines, issued by front groups these Defendants funded and controlled. These 2009 Guidelines are still available online today.[77]

181. The **Alliance for Patient Access** (APA), discussed above, was established in 2006, along with the firm that runs it, Woodberry Associates LLC. The APA describes itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care," but its list of "Associate Members and Financial Supporters" contains thirty drug companies, including each of the Manufacturing Defendants named in this lawsuit. In addition, the APA's board members include doctors who have received hundreds of thousands of dollars in payments from drug companies. As discussed above, the APA has been a vocal critic of policies restricting the flow of opioids and has supported efforts to curtail the DEA's ability to stop suspicious orders of prescription drugs.

182. The "white paper" issued by the APA in 2013 also echoed a favorite narrative of the Manufacturing Defendants, the supposed distinction between "legitimate patients" on the one hand and "addicts" on the other, asserting that one "unintended consequence" of regulating pain medication would be that "[p]atients with legitimate medical needs feel stigmatized, treated like addicts."[78]

183. Another group utilized by the Manufacturing Defendants to encourage opioid prescribing practices, a University of Wisconsin-based organization known as the **Pain & Policy Studies Group**, received $2.5 million from pharmaceutical companies to promote opioid use and discourage the passing of regulations against opioid use in medical practice. The Pain & Policy Studies Group wields considerable influence over the nation's medical schools as well as within

[77] *Clinical Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, Am. Pain Soc'y, http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cncp.pdf (last visited May 22, 2018).

[78] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, *supra* note 47.

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the medical field in general.[79] Purdue was the largest contributor to the Pain & Policy Studies Group, paying approximately $1.6 million between 1999 and 2010.[80]

184. The **Federation of State Medical Boards** (FSMB) of the United States is a national non-profit organization that represents the seventy-state medical and osteopathic boards of the United States and its territories and co-sponsors the United States Medical Licensing Examination. Beginning in 1997, FSMB developed model policy guidelines around the treatment of pain, including opioid use. The original initiative was funded by the Robert Wood Johnson Foundation, but subsequently AAPM, APS, the University of Wisconsin Pain & Policy Studies Group, and the American Society of Law, Medicine, & Ethics all made financial contributions to the project.

185. FSMB's 2004 *Model Policy* encourages state medical boards "to evaluate their state pain policies, rules, and regulations to identify *any regulatory restrictions or barriers that may impede the effective use of opioids* to relieve pain."[81] (Emphasis added).

186. One of the most significant barriers to convincing doctors that opioids were safe to prescribe to their patients for long-term treatment of chronic pain was the fact that many of those patients would, in fact, become addicted to opioids. If patients began showing up at their doctors' offices with obvious signs of addiction, the doctors would, of course, become concerned and likely stop prescribing opioids. And, doctors might stop believing the Manufacturing Defendants' claims that addiction risk was low.

187. To overcome this hurdle, the Manufacturing Defendants promoted a concept called "pseudoaddiction." These Defendants told doctors that when their patients appeared to be addicted to opioids—for example, asking for more and higher doses of opioids, increasing doses

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[79] *The Role of Pharmaceutical Companies in the Opioid Epidemic*, Addictions.com, https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/ (last visited May 22, 2018).

[80] John Fauber, *UW group ends drug firm funds*, Journal Sentinel (Apr. 20, 2011), http://archive.jsonline.com/watchdog/watchdogreports/120331689.html.

[81] *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Fed'n of St. Med. Boards of the U.S., Inc. (May 2004), http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/model04.pdf.

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themselves, or claiming to have lost prescriptions in order to get more opioids—this was not actual addiction. Rather, the Manufacturing Defendants told doctors what appeared to be classic signs of addiction were actually just signs of undertreated pain. The solution to this "pseudoaddiction": more opioids. Instead of warning doctors of the risk of addiction and helping patients to wean themselves off of powerful opioids and deal with their actual addiction, the Manufacturing Defendants pushed even more dangerous drugs onto patients.

188. The FSMB's *Model Policy* gave a scientific veneer to this fictional and overstated concept. The policy defines "pseudoaddiction" as "[t]he iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction" and states that these behaviors "resolve upon institution of effective analgesic therapy."[82]

189. In May 2012, Senate Finance Committee Chairman Max Baucus and senior Committee member Chuck Grassley initiated an investigation into the connections of the Manufacturing Defendants with medical groups and physicians who have advocated increased opioid use.[83] In addition to Purdue, Endo, and Janssen, the senators sent letters to APF, APS, AAPM, FSMB, the University of Wisconsin Pain & Policy Studies Group, the Joint Commission on Accreditation of Healthcare Organization, and the Center for Practical Bioethics, requesting from each "a detailed account of all payments/transfers received from corporations and any related corporate entities and individuals that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 to the present."[84]

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[82] *Id.*

[83] *Baucus, Grassley Seek Answers about Opioid Manufacturers' Ties to Medical Groups*, U.S. Senate Comm. on Fin. (May 8, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups.

[84] Letter from U.S. Senate Comm. on Fin. to Am. Pain Found. (May 8, 2012), https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Foundation2.pdf.

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190. On the same day as the senators' investigation began, APF announced that it would "cease to exist, effective immediately."[85]

3. "It was pseudoscience": the Manufacturing Defendants paid prominent physicians to promote their products.

191. The Manufacturing Defendants retained highly credentialed medical professionals to promote the purported benefits and minimal risks of opioids. Known as "Key Opinion Leaders" or "KOLs," these medical professionals were often integrally involved with the front groups described above. The Manufacturing Defendants paid these KOLs substantial amounts to present at Continuing Medical Education ("CME") seminars and conferences, and to serve on their advisory boards and on the boards of the various front groups.

192. The Manufacturing Defendants also identified doctors to serve as speakers or attend all-expense-paid trips to programs with speakers.[86] The Manufacturing Defendants used these trips and programs—many of them lavish affairs—to incentivize the use of opioids while downplaying their risks, bombarding doctors with messages about the safety and efficacy of opioids for treating long-term pain. Although often couched in scientific certainty, the Manufacturing Defendants' messages were false and misleading, and helped to ensure that millions of Americans would be exposed to the profound risks of these drugs.

193. It is well documented that this type of pharmaceutical company symposium influences physicians' prescribing, even though physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.[87] For example, doctors who were invited to these all-expenses-paid weekends in resort locations like Boca Raton, Florida, and Scottsdale, Arizona, wrote twice as many prescriptions as those who did not attend.[88]

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[85] Charles Ornstein and Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57pm), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

[86] Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 68.

[87] *Id.*

[88] Harriet Ryan, Lisa Girion and Scott Glover, *OxyContin goes global — "We're only just getting started"*, Los Angeles Times (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/.

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194. The KOLs gave the impression they were independent sources of unbiased information, while touting the benefits of opioids through their presentations, articles, and books. KOLs also served on committees and helped develop guidelines such as the 2009 Guidelines described above that strongly encouraged the use of opioids to treat chronic pain.

195. One of the most prominent KOLs for the Manufacturing Defendants' opioids was Dr. Russell Portenoy. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"[89]

196. As one organizer of CME seminars, who worked with Portenoy and Purdue, pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."[90]

197. In recent years, some of the Manufacturing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.[91] Dr. Portenoy himself specifically admitted that he overstated the drugs' benefits and glossed over their risks, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[92] He mused, "Did I teach about pain management, specifically about

[89] Quinones, *supra* note 48, at 314.

[90] *Id.* at 136.

[91] *See, e.g.*, John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (finding that a key Endo KOL acknowledged that opioid marketing went too far).

[92] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012, 11:36am), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

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opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . . We didn't know then what we know now."[93]

198. Dr. Portenoy did not need "the standards of 2012" to discern evidence-based science from baseless claims, however. When interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."[94]

199. Dr. Portenoy was perhaps the most prominent KOL for prescription opioids, but he was far from the only one. In fact, Dr. Portenoy and a doctor named Perry Fine co-wrote *A Clinical Guide to Opioid Analgesia*, which contained statements that conflict with the CDC's 2016 *Guideline for Prescribing Opioids for Chronic Pain*, such as the following examples regarding respiratory depression and addiction:

> At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
>
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (ie, for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[95]

200. Dr. Fine is a Professor of Anesthesiology at the University of Utah School of Medicine's Pain Research Center. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.[96]

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[93] *Id.*

[94] Meier, *supra* note 20, at 277.

[95] Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

[96] Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true.

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201. In 2011, he and Dr. Scott Fishman, discussed below, published a letter in *JAMA* called "Reducing Opioid Abuse and Diversion," which emphasized the importance of maintaining patient access to opioids.[97] The editors of *JAMA* found that both doctors had provided incomplete financial disclosures and made them submit corrections listing all of their ties to the prescription painkiller industry.[98]

202. Dr. Fine also failed to provide full disclosures as required by his employer, the University of Utah. For example, Dr. Fine told the university that he had received under $5,000 in 2010 from Johnson & Johnson for providing "educational" services, but Johnson & Johnson's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year.[99]

203. In 2012, along with other KOLs, Dr. Fine was investigated for his ties to drug companies as part of the Senate investigation of front groups described above. When Marianne Skolek, a reporter for the online news outlet Salem-News.com and a critic of opioid overuse, wrote an article about him and another KOL being investigated, Dr. Fine fired back, sending a letter to her editor accusing her of poor journalism and saying that she had lost whatever credibility she may have had. He criticized her for linking him to Purdue, writing, "I have never had anything to do with Oxycontin development, sales, marketing or promotion; I have never been a Purdue Pharma speaker"—neglecting to mention, of course, that he served on Purdue's advisory board, as the *JAMA* editors had previously forced him to disclose. [100]

204. Another Utah physician, Dr. Lynn Webster, was the director of Lifetree Clinical Research & Pain Clinic in Salt Lake City from 1990 to 2010, and in 2013 was the president of AAPM (one of the front groups discussed above). Dr. Webster developed a five-question survey

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[97] Perry G. Fine, MD and Scott M. Fishman, MD, *Reducing Opioid Abuse and Diversion*, 306 (4) JAMA 381 (July 27, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104144?redirect=true.

[98] *Incomplete Financial Disclosures in: Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1446 (Oct. 5, 2011), https://jamanetwork.com/journals/jama/fullarticle/1104453.

[99] Weber and Ornstein, *Two Leaders in Pain Treatment*, *supra* note 76.

[100] Marianne Skolek, *Doctor Under Senate Investigation Lashes Out at Journalist*, Salem News (Aug. 12, 2012, 8:45pm), http://www.salem-news.com/articles/august122012/perry-fine-folo-ms.php.

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he called the Opioid Risk Tool, which he asserted would "predict accurately which individuals may develop aberrant behaviors when prescribed opioids for chronic pain."[101] He published books titled *The Painful Truth: What Chronic Pain Is Really Like and Why It Matters to Each of Us* and *Avoiding Opioid Abuse While Managing Pain*.

205. Dr. Webster and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the opioid industry's promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills. Tina Webb, a Lifetree patient who overdosed in 2007, was taking as many as thirty-two pain pills a day in the year before she died, all while under doctor supervision.[102] Carol Ann Bosley, who sought treatment for pain at Lifetree after a serious car accident and multiple spine surgeries, quickly became addicted to opioids and was prescribed increasing quantities of pills; at the time of her death, she was on seven different medications totaling approximately 600 pills a month.[103] Another woman, who sought treatment from Lifetree for chronic low back pain and headaches, died at age forty-two after Lifetree clinicians increased her prescriptions to fourteen different drugs, including multiple opioids, for a total of 1,158 pills a month.[104]

206. By these numbers, Lifetree resembles the pill mills and "bad actors" that the Manufacturing Defendants blame for opioid overuse. But Dr. Webster was an integral part of Defendants' marketing campaigns, a respected pain specialist who authored numerous CMEs sponsored by Endo and Purdue. And the Manufacturing Defendants promoted his Opioid Risk

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[101] Lynn Webster and RM Webster, *Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool* 6 (6) Pain Med. 432 (Nov.-Dec. 2005), https://www.ncbi.nlm.nih.gov/pubmed/16336480.

[102] Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, Deseret News (Oct. 26, 2017, 12:01am), https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html.

[103] Stephanie Smith, *Prominent pain doctor investigated by DEA after patient deaths*, CNN (Dec. 20, 2013, 7:06am), http://www.cnn.com/2013/12/20/health/pain-pillar/index.html.

[104] *Id.*

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Tool and similar screening questionnaires as measures that allow powerful opioids to be prescribed for chronic pain.

207. Even in the face of patients' deaths, Dr. Webster continues to promote a pro-opioid agenda, even asserting that alternatives to opioids are risky because "[i]t's not hard to overdose on NSAIDs or acetaminophen."[105] He argued on his website in 2015 that DEA restrictions on the accessibility of hydrocodone harm patients, and in 2017 tweeted in response to CVS Caremark's announcement that it will limit opioid prescriptions that "CVS Caremark's new opioid policy is wrong, and it won't stop illegal drugs."[106]

208. Another prominent KOL is Dr. Scott M. Fishman, the Chief of the Department of Pain Medicine at University of California, Davis. He has served as president of APF and AAPM, and as a consultant and a speaker for Purdue, in addition to providing the company grant and research support. He also has had financial relationships with Endo and Janssen. He wrote a book for the FSMB called *Responsible Opioid Use: A Physician's Guide*, which was distributed to over 165,000 physicians in the U.S.

209. Dr. Fishman and Dr. Fine, along with Dr. Seddon Savage, published an editorial in the Seattle Times in 2010, arguing that Washington legislation proposed to combat prescription opioid abuse would harm patients, in particular by requiring chronic pain patients to consult with a pain specialist before receiving a prescription for a moderate to high dose of an opioid.[107]

210. These KOLs and others—respected specialists in pain medicine—proved to be highly effective spokespeople for the Manufacturing Defendants.

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[105] *APF releases opioid medication safety module*, Drug Topics (May 10, 2011), http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/apf-releases-opioid-medication-safety-module.

[106] Lynn Webster, MD (@LynnRWebsterMD), Twitter (Dec. 7, 2017, 5:45pm), https://twitter.com/LynnRWebsterMD/status/938887130545360898.

[107] Perry G. Fine, Scott M. Fishman, and Seddon R. Savage, *Bill to combat prescription abuse really will harm patients in pain*, Seattle Times (Mar. 16, 2010, 4:39pm), http://old.seattletimes.com/html/opinion/2011361572_guest17fine.html.

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4. The Manufacturing Defendants used "unbranded" advertising as a platform for their misrepresentations about opioids.

211. The Manufacturing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product. A trick often used by pharmaceutical companies, unbranded advertising gives the pharmaceutical companies considerable leeway to make sweeping claims about health conditions or classes of drugs. In contrast, a "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label.

212. Unbranded advertising allows pharmaceutical manufacturers to sidestep those requirements; "fair balance" and consistency with a drug's label are not required.

213. By engaging in unbranded advertising, the Manufacturing Defendants were and are able to avoid FDA review and issue general statements to the public including that opioids improve function, that addiction usually does not occur, and that withdrawal can easily be managed. The Manufacturing Defendants' unbranded advertisements either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

214. Through the various marketing channels described above—all of which the Manufacturing Defendants controlled, funded, and facilitated, and for which they are legally responsible—these Defendants made false or misleading statements about opioids despite the lack of scientific evidence to support their claims, while omitting the true risk of addiction and death.

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D. Specific Misrepresentations Made by the Manufacturing Defendants.

215. All the Manufacturing Defendants have made and/or continue to make false or misleading claims in the following areas: (1) the low risk of addiction to opioids, (2) opioids' efficacy for chronic pain and ability to improve patients' quality of life with long-term use, (3) the lack of risk associated with higher dosages of opioids, (4) the need to prescribe more opioids to treat withdrawal symptoms, and (5) that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe opioids for chronic use. These illustrative but non-exhaustive categories of the Manufacturing Defendants' misrepresentations about opioids are described in detail below.

1. The Manufacturing Defendants falsely claimed that the risk of opioid abuse and addiction was low.

216. Collectively, the Manufacturing Defendants have made a series of false and misleading statements about the low risk of addiction to opioids over the past twenty years. The Manufacturing Defendants have also failed to take sufficient remedial measures to correct their false and misleading statements.

217. The Manufacturing Defendants knew that many physicians were hesitant to prescribe opioids other than for acute or cancer-related pain because of concerns about addiction. Because of this general perception, sales messaging about the low risk of addiction was a fundamental prerequisite misrepresentation.

218. Purdue launched OxyContin in 1996 with the statement that OxyContin's patented continuous-release mechanism "is believed to reduce the abuse liability." This statement, which appeared in OxyContin's label and which sales representatives were taught to repeat verbatim, was unsupported by any studies, and was patently false. The continuous-release mechanism was simple to override, and the drug correspondingly easy to abuse. This fact was known, or should have been known, to Purdue prior to its launch of OxyContin, because people had been circumventing the same continuous-release mechanism for years with MS Contin,

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which in fact commanded a high street price because of the dose of pure narcotic it delivered. In addition, with respect to OxyContin, Purdue researchers notified company executives, including Raymond and Richard Sackler, by email that patients in their clinical trials were abusing the drug despite the timed-release mechanism.[108]

219. In 2007, as noted above, Purdue pleaded guilty to misbranding a drug, a felony under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(a)(2). As part of its guilty plea, Purdue agreed that certain Purdue supervisors and employees had, "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications" in the following ways:

> Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;
>
> Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
>
> Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
>
> Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[109]

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[108] WBUR On Point interview, *supra* note 26.

[109] *United States v. Purdue Frederick Co.*, *supra* note 30*; see also*, Plea Agreement, *United States v. Purdue Frederick Co*., No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

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220. All of these statements were false and misleading. But Purdue had not stopped there. Purdue—and later the other Defendants—manipulated scientific research and utilized respected physicians as paid spokespeople to convey its misrepresentations about low addiction risk in much more subtle and pervasive ways, so that the idea that opioids used for chronic pain posed a low addiction risk became so widely accepted in the medical community that Defendants were able to continue selling prescription opioids for chronic pain—even after Purdue's criminal prosecution.

221. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

222. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids.[110] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

[110] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

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ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

223. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study, and that one could not conclude anything about long-term use of opioids from his figures.[111] Dr. Jick also recalled that no one from drug companies or patient advocacy groups contacted him for more information about the data.[112]

224. Nonetheless, the Manufacturing Defendants regularly invoked this letter as proof of the low addiction risk in connection with taking opioids despite its obvious shortcomings. These Defendants' egregious misrepresentations based on this letter included claims that *less than one percent* of opioid users become addicted.

225. The limited facts of the study did not deter the Manufacturing Defendants from using it as definitive proof of opioids' safety. The enormous impact of the Manufacturing Defendants' misleading amplification of this letter was well documented in another letter

[111] Meier, *supra* note 20, at 174.
[112] *Id.*

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published in NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .[113]

226. Unfortunately, by the time of this analysis and the CDC's findings in 2016, the damage had already been done. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[114]

227. The Manufacturing Defendants successfully manipulated the 1980 Porter and Jick letter as the "evidence" supporting their fundamental misrepresentation that the risk of opioid addiction was low when opioids were prescribed to treat pain. For example, in its 1996 press release announcing the release of OxyContin, Purdue advertised that the "fear of addiction is exaggerated" and quoted the chairman of the American Pain Society Quality of Care Committee, who claimed that "there is very little risk of addiction from the proper uses of these [opioid] drugs for pain relief."[115]

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[113] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

[114] *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT News (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

[115] Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/.

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PR Newswire

May 31, 1996, Friday - 15:47 Eastern Time

NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM PERSISTENT

The fear of addiction is exaggerated.

One cause of patient resistance to appropriate pain treatment -- the fear of addiction -- is largely unfounded. According to Dr. Max, "Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief."

Paul D. Goldenheim, M.D., Vice President of Purdue Pharma L.P. in Norwalk, Connecticut, agrees with this assessment. "Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use."

228. Dr. Portenoy, the Purdue KOL mentioned previously, also stated in a promotional video from the 1990s that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[116]

[116] Catan and Perez, *supra* note 92.

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229. Purdue also specifically used the Porter and Jick letter in its 1998 promotional video, "I got my life back," in which Dr. Alan Spanos says, "In fact, the rate of addiction amongst pain patients who are treated by doctors is *much less than 1%*."[117]

230. The Porter and Jick letter was also used on Purdue's "Partners Against Pain" website, which was available in the early 2000s, where Purdue claimed that the addiction risk with OxyContin was very low.[118]

231. The Porter and Jick letter was used frequently in literature given to prescribing physicians and to patients who were prescribed OxyContin.[119]

232. In addition to the Porter and Jick letter, the Manufacturing Defendants exaggerated the significance of a study published in 1986 regarding cancer patients treated with opioids. Conducted by Dr. Portenoy and another pain specialist, Dr. Kathleen Foley, the study involved only 38 patients, who were treated for non-malignant cancer pain with low doses of opioids (the majority were given less than 20 MME/day, the equivalent of only 13 mg of

[117] Our Amazing World, *Purdue Pharma OxyContin Commercial*, https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited May 22, 2018) (emphasis added).

[118] Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 68.

[119] Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma's Marketing* (Aug. 22, 2001), https://web.archive.org/web/20170212210143/https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf.

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oxycodone).[120] Of these thirty-eight patients, only two developed problems with opioid abuse, and Dr. Portenoy and Dr. Foley concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."[121] Notwithstanding the small sample size, low doses of opioids involved, and the fact that all the patients were cancer patients, the Manufacturing Defendants used this study as "evidence" that high doses of opioids were safe for the treatment of chronic non-cancer pain.

233. The Manufacturing Defendants' repeated misrepresentations about the low risk of opioid addiction were so effective that this concept became part of the conventional wisdom. Dr. Nathaniel Katz, a pain specialist, recalls learning in medical school that previous fears about addiction were misguided, and that doctors should feel free to allow their patients the pain relief that opioids can provide. He did not question this until one of his patients died from an overdose. Then, he searched the medical literature for evidence of the safety and efficacy of opioid treatment for chronic pain. "There's not a shred of research on the issue. All these so-called experts in pain are dedicated and have been training me that opioids aren't as addictive as we thought. But what is that based on? It was based on nothing."[122]

234. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue continued to emphasize "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[123]

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[120] Russell K. Portenoy and Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 Pain 171-86 (1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550.

[121] *Id.*

[122] Quinones, *supra* note 48, at 188-89.

[123] *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice

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235. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question, "Aren't opioid pain medications like OxyContin Tablets 'addicting'? Even my family is concerned about this," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

236. Similarly, Dr. David Haddox, Senior Medical Director for Purdue, cavalierly stated, "[w]hen this medicine is used appropriately to treat pain under a doctor's care, it is not only effective, it is safe."[124] He went so far as to compare OxyContin to celery, because even celery would be harmful if injected: "If I gave you a stalk of celery and you ate that, it would be healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[125]

237. Purdue sales representatives also repeated these misstatements regarding the low risk for addiction to doctors across the country.[126] Its sales representatives targeted primary care physicians in particular, downplaying the risk of addiction and, as one doctor observed, "promot[ing] among primary care physicians a more liberal use of opioids."[127]

238. Purdue sales representatives were instructed to "distinguish between iatrogenic addiction (<1% of patients) and substance abusers/diversion (about 10% of the population abuse something: weed; cocaine; heroin; alcohol; valium; etc.)."[128]

President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

[124] Roger Alford, *Deadly OxyContin abuse expected to spread in the U.S.*, Charleston Gazette, Feb. 9, 2001.

[125] *Id.*

[126] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, New York Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.

[127] Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 68.

[128] Meier, *supra* note 20, at 269.

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239. Purdue also marketed OxyContin for a wide variety of conditions and to doctors who were not adequately trained in pain management.[129]

240. As of 2003, Purdue's Patient Information guide for OxyContin contained the following language regarding addiction:

> Concerns about abuse, addiction, and diversion should not prevent the proper management of pain. The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However, data are not available to establish the true incidence of addiction in chronic pain patients.

241. Although Purdue has acknowledged it has made some misrepresentations about the safety of its opioids,[130] it has done nothing to address the ongoing harms of their misrepresentations; in fact, it continues to make those misrepresentations today.

242. Defendant Endo also made dubious claims about the low risk of addiction. For instance, it sponsored a website, PainKnowledge.com, on which in 2009 it claimed that "[p]eople who take opioids as prescribed usually do not become addicted."[131] The website has since been taken down.

243. In another website, PainAction.com—which is still currently available today—Endo also claimed that "most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[132]

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[129] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 35.

[130] Following the conviction in 2007 of three of its executives for misbranding OxyContin, Purdue released a statement in which they acknowledged their false statements. "Nearly six years and longer ago, some employees made, or told other employees to make, certain statements about OxyContin to some health care professionals that were inconsistent with the F.D.A.-approved prescribing information for OxyContin and the express warnings it contained about risks associated with the medicine. The statements also violated written company policies requiring adherence to the prescribing information."

[131] German Lopez, *The growing number of lawsuits against opioid companies, explained*, Vox (Feb. 27, 2018, 2:25pm), https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits.

[132] *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), https://www.painaction.com/opioid-medication-addiction/.

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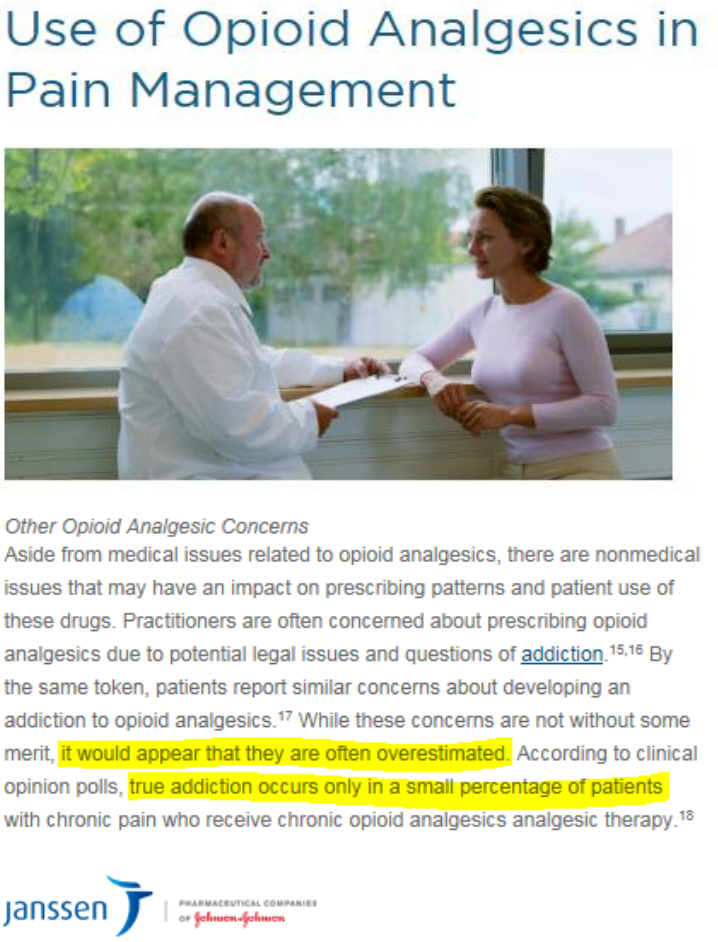
244. In a pamphlet titled "Understanding Your Pain: Taking Oral Opioid Analgesics," Endo assured patients that addiction is something that happens to people who take opioids for reasons other than pain relief, "such as unbearable emotional problems"[133]:

245. In addition, Endo made statements in pamphlets and publications that most health care providers who treat people with pain agree that most people do not develop an addiction problem. These statements also appeared on websites sponsored by Endo, such as Opana.com. In



Use of Opioid Analgesics in Pain Management

Other Opioid Analgesic Concerns

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.[15,16] By the same token, patients report similar concerns about developing an addiction to opioid analgesics.[17] While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.[18]

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

its currently active website, PrescribeResponsibly.com, Defendant Janssen states that concerns

[133] *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharms. (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

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about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[134]

246. Similarly, in a 2009 patient education video titled "Finding Relief: Pain Management for Older Adults," Janssen sponsored a video by the American Academy of Pain Medicine that indicated that opioids are rarely addictive. The video has since been taken down.[135]

247. Janssen also approved and distributed a patient education guide in 2009 that attempted to counter the "myth" that opioids are addictive, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[136]

248. In addition, all the Manufacturing Defendants used third parties and front groups to further their false and misleading statements about the safety of opioids.

249. For example, in testimony for the Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits, in front of the Senate Health, Education, Labor and Pensions Committee in February 2002, Dr. John D. Giglio, Executive Director of the APF, the organization which, as described above, received the majority of its funding from opioid manufacturers, including Purdue, stated that "opioids are safe and effective, and only in rare cases lead to addiction."[137] Along with Dr. Giglio's testimony, the APF submitted a short background sheet on "the scope of the undertreatment of pain in the U.S.," which asserted that "opioids are often the best" treatment for pain that hasn't responded to other techniques, but that patients and many doctors "lack even basic knowledge about these options and fear that powerful pain drugs will [c]ause addiction." According to the APF, "most studies show that less than 1%

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[134] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified July 2, 2015).

[135] Molly Huff, *Finding Relief: Pain Management for Older Adults*, Ctrs. for Pain Mgmt. (Mar. 9, 2011), http://www.managepaintoday.com/news/-Finding-Relief-Pain-Management-for-Older-Adults.

[136] Lopez, *supra* note 131.

[137] *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain Foundation), https://www.help.senate.gov/imo/media/doc/Giglio.pdf.

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of patients become addicted, which is medically different from becoming physically dependent."[138]

250. The APF further backed up Purdue in an amicus curiae brief filed in an Ohio appeals court in December 2002, in which it claimed that "medical leaders have come to understand that the small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients."[139]

251. In a 2007 publication titled "Treatment Options: A Guide for People Living with Pain," APF downplayed the risk of addiction and argued that concern about this risk should not prevent people from taking opioids: "Restricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."[140] APF also tried to normalize the dangers of opioids by listing opioids as one of several "[c]ommon drugs that can cause physical dependence," including steroids, certain heart medications, and caffeine.[141]

252. The Manufacturing Defendants' repeated statements about the low risk of addiction when taking opioids as prescribed for chronic pain were blatantly false and were made with reckless disregard for the potential consequences.

2. The Manufacturing Defendants falsely claimed that opioids were proven effective for chronic pain and would improve quality of life.

253. Not only did the Manufacturing Defendants falsely claim that the risk of addiction to prescription opioids was low, these Defendants represented that there was a significant upside

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[138] *Id.*

[139] Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf.

[140] *Treatment Options: A Guide for People Living with Pain*, Am. Pain Found., https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited May 22, 2018).

[141] *Id.*

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to long-term opioid use, including that opioids could restore function and improve quality of life.[142]

254. Such claims were viewed as a critical part of the Manufacturing Defendants' marketing strategies. For example, an internal Purdue report from 2001 noted the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine . . . We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[143]

255. Despite the lack of data supporting improvement in quality of life, Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association in 2002, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson.[144] This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[145]

256. Purdue also consistently tried to steer any concern away from addiction and focus on its false claims that opioids were effective and safe for treating chronic pain. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Michael Friedman, Executive Vice President and Chief Operating Officer of Purdue, testified that "even the most vocal critics of opioid therapy concede the value of OxyContin in the legitimate treatment of pain," and that

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[142] This case *does not* request or require the Court to specifically adjudicate whether opioids are appropriate for the treatment of chronic, non-cancer pain—though the scientific evidence strongly suggests they are not.

[143] Meier, *supra* note 20, at 281.

[144] *Id.* at 280.

[145] Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, Wall Street Journal (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824.

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"OxyContin has proven itself an effective weapon in the fight against pain, returning many patients to their families, to their work, and to their ability to enjoy life."[146]

257. Purdue sponsored the development and distribution of an APF guide in 2011 which claimed that "multiple clinical studies have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." This guide is still available today.

258. Purdue also ran a series of advertisements of OxyContin in 2012 in medical journals titled "Pain vignettes," which were styled as case studies of patients with persistent pain conditions and for whom OxyContin was recommended to improve their function.

259. Purdue and Endo also sponsored and distributed a book in 2007 to promote the claim that pain relief from opioids, by itself, improved patients' function. The book remains for sale online today.

260. Endo's advertisements for Opana ER claimed that use of the drug for chronic pain allowed patients to perform demanding tasks like construction and portrayed Opana ER users as healthy and unimpaired.

261. Endo's National Initiative on Pain Control (NIPC) website also claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."

262. Endo further sponsored a series of CME programs through NIPC which claimed that chronic opioid therapy has been "shown to reduce pain and depressive symptoms and cognitive functioning."

[146] *Oxycontin: Its Use and Abuse, supra* note 123.

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263. Through PainKnowledge.org, Endo also supported and sponsored guidelines that stated, among other things, that "Opioid Medications are a powerful and often highly effective tool in treating pain," and that "they can help restore comfort, function, and quality of life."[147]

264. In addition, Janssen sponsored and edited patient guides which stated that "opioids may make it easier for people to live normally." The guides listed expected functional improvements from opioid use, including sleeping through the night, and returning to work, recreation, sex, walking, and climbing stairs.

265. Janssen also sponsored, funded, and edited a website which featured an interview edited by Janssen that described how opioids allowed a patient to "continue to function." This video is still available today.

266. Furthermore, sales representatives for the Manufacturing Defendants communicated and continue to communicate the message that opioids will improve patients' function, without appropriate disclaimers.

267. The Manufacturing Defendants' statements regarding opioids' ability to improve function and quality of life are false and misleading. As the CDC's *Guideline for Prescribing Opioids for Chronic Pain* (the "2016 CDC Guideline" or "Guideline")[148] confirms, not a single study supports these claims.

268. In fact, to date, there have been no long-term studies that demonstrate that opioids are effective for treating long-term or chronic pain. Instead, reliable sources of information, including from the CDC in 2016, indicate that there is "*[n]o evidence*" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain."[149] By contrast, significant research has demonstrated the colossal dangers of opioids. The CDC, for example, concluded that "[e]xtensive evidence shows the possible harms of opioids (including opioid use

[147] *Informed Consent for Using Opioids to Treat Pain*, Painknowledge.org (2007), https://www.mainequalitycounts.org/image_upload/Opioid%20Informed%20Consent%20Formatted_1_23_2008.pdf.

[148] 2016 CDC Guideline, *supra* note 36.

[149] *Id.*

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disorder, overdose, and motor vehicle injury)" and that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[150]

3. The Manufacturing Defendants falsely claimed doctors and patients could increase opioid usage indefinitely without added risk.

269. The Manufacturing Defendants also made false and misleading statements claiming that there is no dosage ceiling for opioid treatment. These misrepresentations were integral to the Manufacturing Defendants' promotion of prescription opioids for two reasons. First, the idea that there was no upward limit was necessary for the overarching deception that opioids are appropriate treatment for chronic pain. As discussed above, people develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Second, the dosing misrepresentation was necessary for the claim that OxyContin and competitor drugs allowed 12-hour dosing.

270. Twelve-hour dosing is a significant marketing advantage for any medication, because patient compliance is improved when a medication only needs to be taken twice a day. For prescription painkillers, the 12-hour dosing is even more significant because shorter-acting painkillers did not allow patients to get a full night's sleep before the medication wore off. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."[151]

271. Purdue executives therefore maintained the messaging of 12-hour dosing even when many reports surfaced that OxyContin did not last 12 hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills.

[150] *Id.*

[151] *OxyContin launch*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/oxycontin-launch-1995/.

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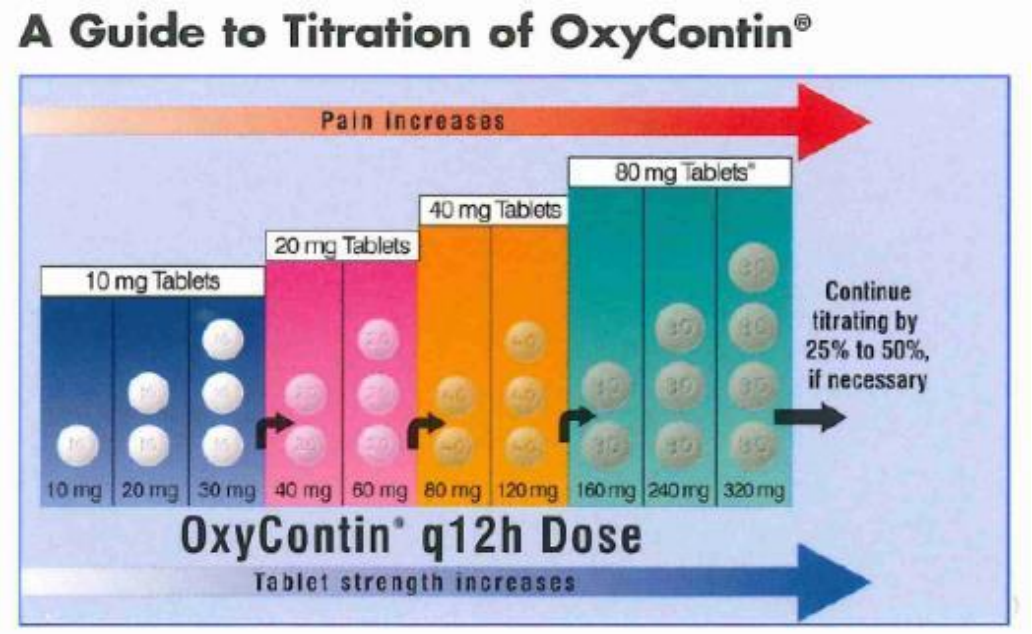
272. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses. The manager directed representatives to discuss with physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."[152]

273. As doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue directed its sales representatives to "refocus" physicians on 12-hour dosing. One sales manager instructed her team that anything shorter "needs to be nipped in the bud. NOW!!"[153]

274. These misrepresentations were incredibly dangerous. As noted above, opioid dosages at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. Notwithstanding the risks, the 2003 Conversion Guide for OxyContin contained the following diagram for increasing dosage up to 320 mg:



[152] *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/.

[153] Harriet Ryan, Lisa Girion, and Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem* (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

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275. In a 2004 response letter to the FDA, Purdue tried to address concerns that patients who took OxyContin more frequently than 12 hours would be at greater risk of side effects or adverse reactions. Purdue contended that the peak plasma concentrations of oxycodone would not increase with more frequent dosing, and therefore no adjustments to the package labeling or 12-hour dosing regimen were needed.[154] But these claims were false, and Purdue's suggestion that there was no upper limit or risk associated with increased dosage was incredibly misleading.

276. Suggesting that it recognized the danger of its misrepresentations of no dose ceiling, Purdue discontinued the OxyContin 160 mg tablet in 2007 and stated that this step was taken "to reduce the risk of overdose accompanying the abuse of this dosage strength."[155]

277. But still Purdue and the other Manufacturing Defendants worked hard to protect their story. In March 2007, Dr. Gary Franklin, Medical Director for the Washington State Department of Labor & Industries, published the *Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain*. Developed in collaboration with providers in Washington State who had extensive experience in the evaluation and treatment of patients with chronic pain, the guideline recommended a maximum daily dose of opioids to protect patients.

278. In response, Purdue sent correspondence to Dr. Franklin specifically indicating, among other things, that "limiting access to opioids for persons with chronic pain is not the answer" and that the "safety and efficacy of OxyContin doses greater than 40 mg every 12 hours in patients with chronic nonmalignant pain" was well established. Purdue even went so far as to represent to Dr. Franklin that even if opioid treatment produces significant adverse effects in a patient, "this does not preclude a trial of another opioid."

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[154] *Purdue Response to FDA, 2004*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/purdue-response-fda-2004/.

[155] *OxyContin Tablets Risk Management Program*, Purdue Pharma L.P., https://web.archive.org/web/20170215064438/https:/www.fda.gov/ohrms/dockets/DOCKETS/07p0232/07p-0232-cp00001-03-Exhibit-02-Part-1-vol1.pdf (revised May 18, 2007).

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279. In 2010, Purdue published a Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, but even the REMS does not address concerns with increasing dosage, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[156]

280. In 2012, APF claimed on its website that there was no "ceiling dose" for opioids for chronic pain.[157] APF also made this claim in a guide sponsored by Purdue, which is still available online.

281. Accordingly, Purdue continued to represent both publicly and privately that increased opioid usage was safe and did not present additional risk at higher doses.

282. Janssen also made the same misrepresentations regarding the disadvantages of dosage limits for other pain medicines in a 2009 patient education guide, while failing to address the risks of dosage increases with opioids.

283. Endo, on a website it sponsors, PainKnowledge.com, also made the claim in 2009 that opioid dosages could be increased indefinitely.

284. In the "Understanding Your Pain" pamphlet discussed above, Endo assures opioid users that concern about developing tolerance to the drugs' pain-relieving effect is "not a problem," and that "[t]he dose can be increased" and "[y]ou won't 'run out' of pain relief."[158]

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[156] *OxyContin Risk Evaluation and Mitigation Strategy,* Purdue Pharma L.P., https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

[157] Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing,* PCHC https://www.mainequalitycounts.org/image_upload/Keynote-%20Managing%20Chronic%20Pain%20and%20Opioids_Nesin.pdf (last visited May 22, 2018).

[158] *Understanding Your Pain: Taking Oral Opioid Analgesics, supra* note 133.

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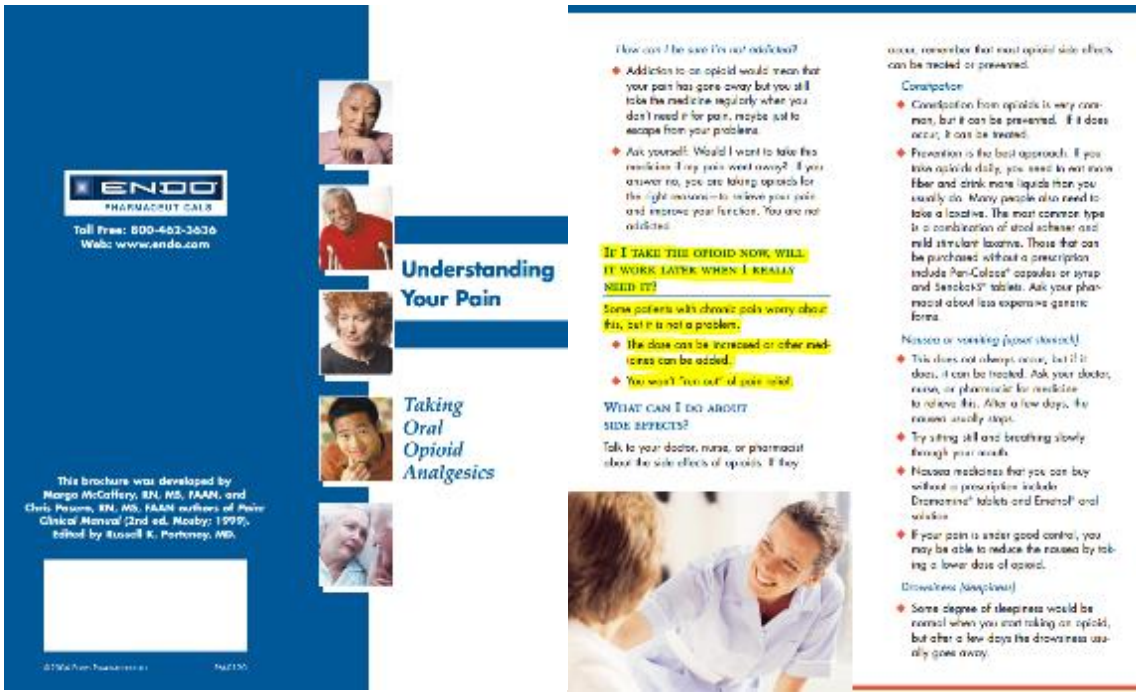

285. Dosage limits with respect to opioids are particularly important not only because of the risk of addiction but also because of the potentially fatal side effect of respiratory depression. Endo's "Understanding Your Pain" pamphlet minimized this serious side effect, calling it "slowed breathing," declaring that it is "very rare" when opioids are used "appropriately," and never stating that it could be fatal:

> *"Slowed breathing"*
>
> - The medical term for "slowed breathing" is "respiratory depression."
> - This is very rare when oral opioids are used appropriately for pain relief.
> - If you become so sleepy that you cannot make yourself stay awake, you may be in danger of slowed breathing. Stop taking your opioid and call your doctor immediately.

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4. The Manufacturing Defendants falsely instructed doctors and patients that more opioids were the solution when patients presented symptoms of addiction.

286. Not only did the Manufacturing Defendants hide the serious risks of addiction associated with opioids, they actively worked to prevent doctors from taking steps to prevent or address opioid addiction in their patients.

287. One way that the Manufacturing Defendants worked to obstruct appropriate responses to opioid addiction was to push a concept called "pseudoaddiction." Dr. David Haddox—who later became a Senior Medical Director for Purdue—published a study in 1989 coining the term, which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[159] ("Iatrogenic" describes a condition induced by medical treatment.) In other words, he claimed that people on prescription opioids who exhibited classic signs of addiction—"abnormal behavior"—were not addicted, but rather simply suffering from under-treatment of their pain. His solution for pseudoaddiction? More opioids.

288. Although this concept was formed based on a single case study, it proved to be a favorite trope in the Manufacturing Defendants' marketing schemes. For example, using this study, Purdue informed doctors and patients that signs of addiction are actually the signs of under-treated pain which should be treated with even more opioids. Purdue reassured doctors and patients, telling them that "chronic pain has been historically undertreated."[160]

289. The Manufacturing Defendants continued to spread the concept of pseudoaddiction through the APF, which even went so far as to compare opioid addicts to coffee drinkers. In a 2002 court filing, APF wrote that "[m]any pain patients (like daily coffee drinkers) claim they are 'addicted' when they experience withdrawal symptoms associated with physical

[159] David E. Weissman and J. David Haddox, *Opioid pseudoaddiction--an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565.
[160] *Oxycontin: Its Use and Abuse, supra* note 123.

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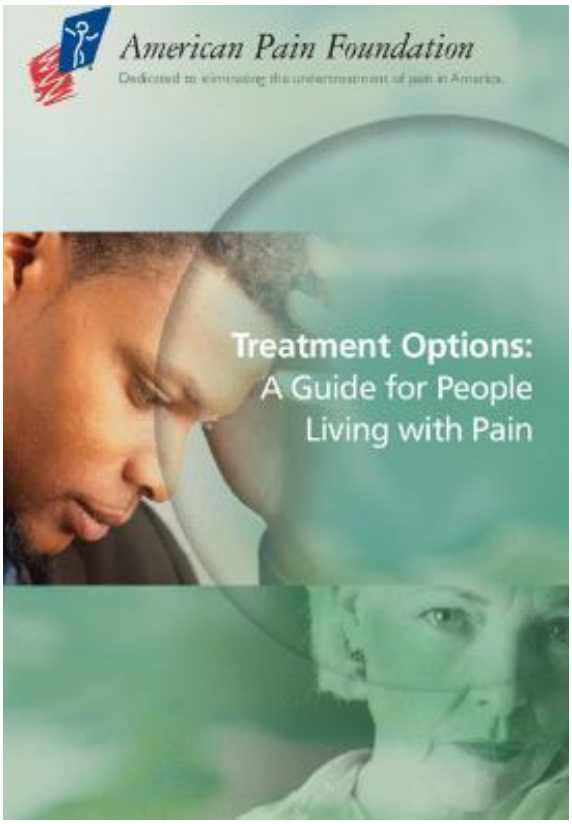
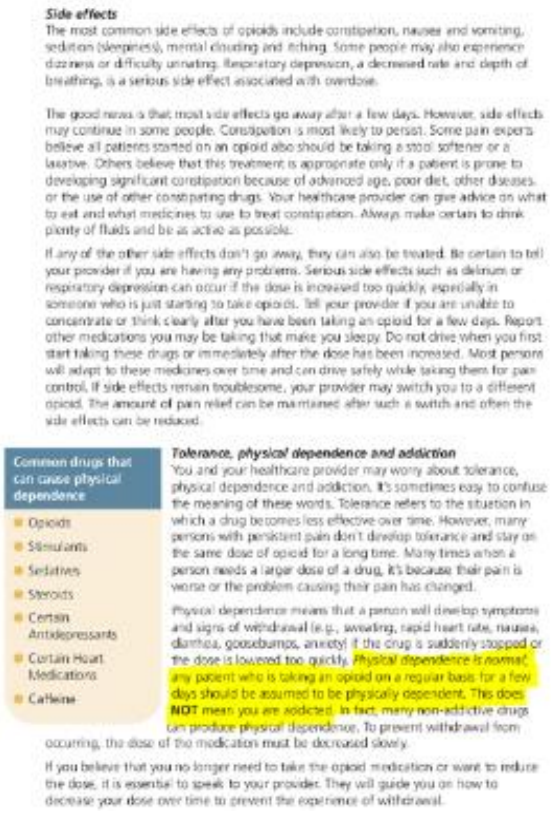
dependence as they decrease their dose. But unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain . . .”[161]

290. In a 2007 publication titled “Treatment Options: A Guide for People Living with Pain,” the APF claimed: “*Physical dependence is normal*; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted.”[162] In this same publication, the APF asserted that “people who are not substance abusers” may also engage in “unacceptable” behaviors such as “increasing the dose without permission or obtaining the opioid from multiple sources,” but that such behaviors do not indicate addiction and instead reflect a “desire to obtain pain relief.”[163]





Side effects

The most common side effects of opioids include constipation, nausea and vomiting, sedation (sleepiness), mental clouding and itching. Some people may also experience dizziness or difficulty urinating. Respiratory depression, a decreased rate and depth of breathing, is a serious side effect associated with overdose.

The good news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is most likely to persist. Some pain experts believe all patients started on an opioid also should be taking a stool softener or a laxative. Others believe that this treatment is appropriate only if a patient is prone to developing significant constipation because of advanced age, poor diet, other diseases, or the use of other constipating drugs. Your healthcare provider can give advice on what to eat and what medicines to use to treat constipation. Always make certain to drink plenty of fluids and be as active as possible.

If any of the other side effects don't go away, they can also be treated. Be certain to tell your provider if you are having any problems. Serious side effects such as delirium or respiratory depression can occur if the dose is increased too quickly, especially in someone who is just starting to take opioids. Tell your provider if you are unable to concentrate or think clearly after you have been taking an opioid for a few days. Report other medications you may be taking that make you sleepy. Do not drive when you first start taking these drugs or immediately after the dose has been increased. Most persons will adapt to these medicines over time and can drive safely while taking them for pain control. If side effects remain troublesome, your provider may switch you to a different opioid. The amount of pain relief can be maintained after such a switch and often the side effects can be reduced.

Common drugs that can cause physical dependence

- Opioids
- Stimulants
- Sedatives
- Steroids
- Certain Antidepressants
- Certain Heart Medications
- Caffeine

Tolerance, physical dependence and addiction

You and your healthcare provider may worry about tolerance, physical dependence and addiction. It's sometimes easy to confuse the meaning of these words. Tolerance refers to the situation in which a drug becomes less effective over time. However, many persons with persistent pain don't develop tolerance and stay on the same dose of opioid for a long time. Many times when a person needs a larger dose of a drug, it's because their pain is worse or the problem causing their pain has changed.

Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, gooseburnps, anxiety) if the drug is suddenly stopped or the dose is lowered too quickly. *Physical dependence is normal*; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted. In fact, many non-addictive drugs can produce physical dependence. To prevent withdrawal from occurring, the dose of the medication must be decreased slowly.

If you believe that you no longer need to take the opioid medication or want to reduce the dose, it is essential to speak to your provider. They will guide you on how to decrease your dose over time to prevent the experience of withdrawal.

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[161] APF Brief Amici Curiae, *supra* note 139, at 10-11.

[162] *Treatment Options: A Guide for People Living with Pain*, *supra* note 140.

[163] *Id.*

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291. Purdue published a REMS for OxyContin in 2010, and in the associated Healthcare Provider Training Guide stated that "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."[164]

292. Purdue worked, and continues to work, to create confusion about what addiction is. For example, Purdue continues to emphasize that abuse and addiction are separate and distinct from physical dependence. Regardless of whether these statements may be technically correct, they continue to add ambiguity over the risks and benefits of opioids.

293. Endo sponsored an NIPC CME program in 2009 which promoted the concept of pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding its projects, developing content, and reviewing NIPC materials.

294. A 2001 paper which was authored by a doctor affiliated with Janssen stated that "[m]any patients presenting to a doctor's office asking for pain medications are accused of drug seeking. In reality, most of these patients may be undertreated for their pain syndrome."[165]

295. In 2009, on a website it sponsored, Janssen stated that pseudoaddiction is different from true addiction "because such behaviors can be resolved with effective pain management."[166]

296. Indeed, on its currently active website PrescribeResponsibly.com, Janssen defines pseudoaddiction as "a syndrome that causes patients to seek additional medications due to

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[164] *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 156.

[165] Howard A. Heit, MD, FACP, FASAM, *The truth about pain management: the difference between a pain patient and an addicted patient*, 5 European Journal of Pain 27-29 (2001), http://www.med.uottawa.ca/courses/totalpain/pdf/doc-34.pdf.

[166] Chris Morran, *Ohio: Makers Of OxyContin, Percocet & Other Opioids Helped Fuel Drug Epidemic By Misleading Doctors, Patients*, Consumerist (May 31, 2017, 2:05pm), https://consumerist.com/2017/05/31/ohio-makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/.

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inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases."[167]

297. As set forth in more detail below, these statements were false and misleading as evidenced by, *inter alia*, the findings made by the CDC in 2016. Indeed, there is simply no evidence that pseudoaddiction is a real phenomenon. As research compiled by the CDC and others makes clear, pseudoaddiction is pseudoscience—nothing more than a concept Defendants seized upon to help sell more of their actually addicting drugs.

[167] Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription, Prescribe Responsibly*, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction (last modified July 2, 2015).

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5. The Manufacturing Defendants falsely claimed that risk-mitigation strategies, including tapering and abuse-deterrent technologies, made it safe to prescribe opioids for chronic use.

298. Even when the Manufacturing Defendants acknowledge that opioids pose some risk of addiction, they dismiss these concerns by claiming that addiction can be easily avoided and addressed through simple steps. In order to make prescribers feel more comfortable about starting patients on opioids, the Manufacturing Defendants falsely communicated to doctors that certain screening tools would allow them to reliably identify patients at higher risk of addiction and safely prescribe opioids, and that tapering the dose would be sufficient to manage cessation of opioid treatment. Both assertions are false.

299. For instance, as noted above, Purdue published a REMS for OxyContin in 2010, in which it described certain steps that needed to be followed for safe opioid use. Purdue stressed that all patients should be screened for their risk of abuse or addiction, and that such screening could curb the incidence of addiction.[168]

300. The APF also proclaimed in a 2007 booklet, sponsored in part by Purdue, that "[p]eople with the disease of addiction may abuse their medications, engaging in unacceptable behaviors like increasing the dose without permission or obtaining the opioid from multiple sources, among other things. Opioids get into the hands of drug dealers and persons with an addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even from other people with pain. It is a problem in our society that needs to be addressed through many different approaches."[169]

301. On its current website for OxyContin,[170] Purdue acknowledges that certain patients have higher risk of opioid addiction based on history of substance abuse or mental illness—a statement which, even if accurate, obscures the significant risk of addiction for all

[168] *Oxycontin Risk Evaluation and Mitigation Strategy*, *supra* note 156.
[169] *Treatment Options: A Guide for People Living with Pain*, *supra* note 140.
[170] OxyContin, https://www.oxycontin.com/index.html (last visited May 22, 2018).

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patients, including those without such a history, and comports with statements it has recently made that it is "bad apple" patients, and not the opioids, that are arguably the source of the opioid crisis:

> Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing OxyContin, and monitor all patients receiving OxyContin for the development of these behaviors and conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as OxyContin, but use in such patients necessitates intensive counseling about the risks and proper use of OxyContin along with intensive monitoring for signs of addiction, abuse, and misuse.

302. Additionally, on its current website, Purdue refers to publicly available tools that can assist with prescribing compliance, such as patient-prescriber agreements and risk assessments.[171]

303. Purdue continues to downplay the severity of addiction and withdrawal and claims that dependence can easily be overcome by strategies such as adhering to a tapering schedule to successfully stop opioid treatment. On the current website for OxyContin, it instructs that "[w]hen discontinuing OxyContin, gradually taper the dosage. Do not abruptly discontinue OxyContin."[172] And on the current OxyContin Medication Guide, Purdue also states that one should "taper the dosage gradually."[173] As a general matter, tapering is a sensible strategy for

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[171] *ER/LA Opioid Analgesics REMS*, Purdue, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/rems/ (last visited May 22, 2018).

[172] Oxycontin.com, *supra* note 170.

[173] *OxyContin Full Prescribing Information*, Purdue Pharma LP, http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o (last visited May 22, 2018).

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cessation of treatment with a variety of medications, such as steroids or antidepressants. But the suggestion that tapering is sufficient in the context of chronic use of potent opioids is misleading and dangerous, and sets patients up for withdrawal and addiction.

304. In its "Dear Healthcare Professional" letter in 2010, Purdue instructed doctors to gradually taper someone off OxyContin to prevent signs and symptoms of withdrawal in patients who were physically dependent.[174] Nowhere does Purdue warn doctors or patients that tapering may be inadequate to safely end opioid treatment and avoid addiction.

305. Other Manufacturing Defendants make similar claims. For instance, Endo suggests that risk-mitigation strategies enable the safe prescription of opioids. In its currently active website, Opana.com, Endo states that assessment tools should be used to assess addiction risk, but that "[t]he potential for these risks should not, however, prevent proper management of pain in any given patient."[175]

306. On the same website, Endo makes similar statements about tapering, stating "[w]hen discontinuing OPANA ER, gradually taper the dosage."[176]

307. Janssen also states on its currently active website, PrescribeResponsibly.com, that the risk of opioid addiction "can usually be managed" through tools such as "opioid agreements" between patients and doctors.[177]

308. Each Manufacturing Defendant's statements about tapering misleadingly implied that gradual tapering would be sufficient to alleviate any risk of withdrawal or addiction while taking opioids.

309. The Manufacturing Defendants have also made and continue to make false and misleading statements about the purported abuse-deterrent properties of their opioid pills to

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[174] *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 156.
[175] Opana ER, Endo Pharmaceuticals, Inc., http://www.opana.com (last visited May 22, 2018).
[176] *Id.*
[177] Heit & Gourlay, *supra* note 167.

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suggest these reformulated pills are not susceptible to abuse. In so doing, the Manufacturing Defendants have increased their profits by selling more pills for substantially higher prices.

310. For instance, since at least 2001, Purdue has contended that "abuse resistant products can reduce the incidence of abuse."[178] Its current website touts abuse-deterrent properties by saying they "can make a difference."[179]

311. On August 17, 2015, Purdue announced the launch of a new website, "Team Against Opioid Abuse," which it said was "designed to help healthcare professionals and laypeople alike learn about different abuse-deterrent technologies and how they can help in the reduction of misuse and abuse of opioids."[180] This website appears to no longer be active.

312. A 2013 study which was authored by at least two doctors who at one time worked for Purdue stated that "[a]buse-deterrent formulations of opioid analgesics can reduce abuse."[181] In another study from 2016 with at least one Purdue doctor as an author, the authors claimed that abuse decreased by as much as 99% in some situations after abuse-deterrent formulations were introduced.[182]

313. Interestingly, one report found that the original safety label for OxyContin, which instructed patients not to crush the tablets because it would have a rapid release effect, may have inadvertently given opioid users ideas for techniques to get high from these drugs.[183]

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[178] *Oxycontin: Its Use and Abuse, supra* note 123.

[179] *Opioids with Abuse-Deterrent Properties*, Purdue, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited May 22, 2018).

[180] *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com*, Purdue (Aug. 17, 2015), http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/.

[181] Paul M. Coplan, Hrishikesh Kale, Lauren Sandstrom, Craig Landau, and Howard D. Chilcoat, *Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics*, 22 (12) Pharmacoepidemiol Drug Saf. 1274-82 (Sept. 30, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283730/.

[182] Paul M. Coplan, Howard D. Chilcoat, Stephen Butler, Edward M. Sellers, Aditi Kadakia, Venkatesh Harikrishnan, J. David Haddox, and Richard C. Dart, *The effect of an abuse-deterrent opioid formulation (OxyContin) on opioid abuse-related outcomes in the postmarketing setting*, 100 Clin. Pharmacol. Ther. 275-86 (June 22, 2016), http://onlinelibrary.wiley.com/doi/10.1002/cpt.390/full.

[183] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 35.

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314. In 2012, Defendant Endo replaced the formula for Opana ER with a new formula with abuse-deterrent properties that it claimed would make Opana ER resistant to manipulation from users to snort or inject it. But the following year, the FDA concluded:

> While there is an increased ability of the reformulated version of Opana ER to resist crushing relative to the original formulation, study data show that the reformulated version's extended-release features can be compromised when subjected to other forms of manipulation, such as cutting, grinding, or chewing, followed by swallowing.
>
> Reformulated Opana ER can be readily prepared for injection, despite Endo's claim that these tablets have "resistance to aqueous extraction (i.e., poor syringeability)." It also appears that reformulated Opana ER can be prepared for snorting using commonly available tools and methods.
>
> The postmarketing investigations are inconclusive, and even if one were to treat available data as a reliable indicator of abuse rates, one of these investigations also suggests the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.[184]

315. Despite the FDA's determination that the evidence did not support Endo's claims of abuse-deterrence, Endo advertised its reformulated pills as "crush resistant" and directed its sales representatives to represent the same to doctors. Endo improperly marketed Opana ER as crush-resistant, when Endo's own studies showed that the pill could be crushed and ground. In 2016, Endo reached an agreement with the Attorney General of the State of New York that required Endo to discontinue making such statements.[185]

316. The Manufacturing Defendants' assertions that their reformulated pills could curb abuse were false and misleading, as the CDC's 2016 Guideline, discussed below, confirm.

317. Ultimately, even if a physician prescribes opioids after screening for abuse risk, advising a patient to taper, and selecting brand-name, abuse-deterrent formulations, chronic opioid use still comes with significant risks of addiction and abuse. The Manufacturing

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[184] *FDA Statement: Original Opana ER Relisting Determination*, U.S. Food & Drug Admin. (May 10, 2013), https://wayback.archive-it.org/7993/20171102214123/https://www.fda.gov/Drugs/DrugSafety/ucm351357.htm.

[185] Press Release, Attorney General Eric T. Schneiderman, *A.G. Schneiderman Announces Settlement with Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs* (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

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Defendants' statements to the contrary were designed to create a false sense of security and assure physicians that they could safely prescribe potent narcotics to their patients.

E. Research by Washington State's Department of Labor and Industries Highlights the Falseness of the Manufacturing Defendants' Claims.

318. Contrary to the Manufacturing Defendants' misrepresentations about the benefits and risks of opioids, growing evidence suggests that using opioids to treat chronic pain leads to overall negative outcomes, delaying or preventing recovery and providing little actual relief, all while presenting serious risks of overdose.

319. One place where this evidence surfaced is the Washington State Department of Labor and Industries ("L&I"). The Department of L&I runs the state's workers' compensation program, which covers all employees in the state, other than those who work for large companies and government entities. In 2000, L&I's new chief pharmacist, Jaymie Mai, noticed an increase in prescription of opioids for chronic pain, approximately 50 to 100 cases a month.[186] As she took a closer look at the prescription data, she discovered some of these same workers were dying from opioid overdoses. That workers suffered back pain or sprained knees on the job was nothing new, but workers dying from their pain medication was assuredly not business as usual. Mai reported what she was seeing to L&I's Medical Director, Dr. Gary Franklin.[187]

320. In addition to being L&I's Medical Director, Dr. Franklin is a research professor at the University of Washington in the departments of Environmental Health, Neurology, and Health Services. Dr. Franklin and Mai undertook a thorough analysis of all recorded deaths in the state's workers' comp system. In 2005, they published their findings in the American Journal of Industrial Medicine.[188]

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[186] Quinones, *supra* note 48, at 203.

[187] *Id.*

[188] Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith A. Turner, Ph.D., Deborah Fulton-Kehoe, Ph.D., MPH, and Linda Grant, BSN, MBA, *Opioid dosing trends and mortality in Washington State Workers' Compensation, 1996-2002*, 48 Am J Ind Med 91-99 (2005).

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321. Their research showed that the total number of opioid prescriptions paid for by the Workers' Compensation Program tripled between 1996 and 2006.[189] Not only did the number of prescriptions balloon, so too did the doses; from 1996 to 2002 the mean daily morphine equivalent dose ("MED") nearly doubled, and remained that way through 2006.[190] As injured Washington workers were given more prescriptions of higher doses of opioids, the rates of opioid overdoses among that population jumped, from zero in 1996 to more than twenty in 2005. And in 2009, over thirty people receiving opioid prescriptions through the Workers' Compensation Program died of an opioid overdose.[191]

322. Armed with these alarming statistics, Dr. Franklin, in conjunction with other doctors in Washington, set out to limit the doses of opioids prescribed through the workers' compensation program. As part of that effort, in 2007 the Agency Medical Directors Group launched an Interagency Guideline on Opioid Dosing, aimed at reducing the numbers of opioid overdoses. Through this, and other related efforts, both the rates of opioid prescriptions and the sizes of doses have declined in Washington, beginning in 2009. As opioid prescriptions rates for injured workers have declined, so too has the death rate among this population.[192]

323. Moreover, additional research from L& I showed that the use of opioids to treat pain after an injury actually prevents or slows a patient's recovery.

324. In a study of employees who had suffered a low back injury on the job, Dr. Franklin showed that if an injured worker was prescribed opioids soon after the injury, high doses of opioids, or opioids for more than a week, the employee was far more likely to experience negative health outcomes than the same employee who was not prescribed opioids in these manners.

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[189] Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith Turner, Ph.D., Mark Sullivan, M.D., Ph.D., Thomas Wickizer, Ph.D., and Deborah Fulton-Kehoe, Ph.D., *Bending the Prescription Opioid Dosing and Mortality Curves: Impact of the Washington State Opioid Dosing Guideline*, 55 Am J Ind Med 325, 327 (2012).

[190] *Id*. at 327-28.

[191] *Id*. at 328.

[192] *Id*.

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325. Specifically, the study showed that, after adjusting for the baseline covariates, injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain disabled a year later than workers with similar injuries who received no opioids at all. Similarly, those who received two prescriptions of opioids for the injury were 1.8 times more likely to remain disabled a year after their injury than workers who received no opioids at all, and those receiving daily doses higher than 150 MED were over twice as likely to be on disability a year later, relative to workers who received no opioids.[193]

326. In sum, not only do prescription opioids present significant risks of addiction and overdose, but they also hinder patient recovery after an injury.

327. This dynamic presents problems for employers, too, who bear significant costs when their employees do not recover quickly from workplace injuries. Employers are left without their labor force and may be responsible for paying for the injured employee's disability for long periods of time.

F. The 2016 CDC Guideline and Other Recent Studies Confirm That the Manufacturing Defendants' Statements About the Risks and Benefits of Opioids Are Patently False.

328. Contrary to the statements made by the Manufacturing Defendants in their well-orchestrated campaign to tout the benefits of opioids and downplay their risks, recent studies confirm the Manufacturing Defendants' statements were false and misleading.

329. The CDC issued its *Guideline for Prescribing Opioids for Chronic Pain* on March 15, 2016.[194] The 2016 CDC Guideline, approved by the FDA, "provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer

[193] Franklin, GM, Stover, BD, Turner, JA, Fulton-Kehoe, D, Wickizer, TM, *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202.

[194] 2016 CDC Guideline, *supra* note 36.

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treatment, palliative care, and end-of-life care." The Guideline also assesses the risks and harms associated with opioid use.

330. The 2016 CDC Guideline is the result of a thorough and extensive process by the CDC. The CDC issued the Guideline after it "obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee." The recommendations in the 2016 CDC Guideline were further made "on the basis of a systematic review of the best available evidence . . ."

331. The CDC went through an extensive and detailed process to solicit expert opinions for the Guideline:

> CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the "Core Expert Group" (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology. CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

332. The 2016 Guideline was also peer-reviewed pursuant to "the final information quality bulletin for peer review." Specifically, the Guideline describes the following independent peer-review process:

> [P]eer review requirements applied to this guideline because it provides influential scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations. CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review

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> process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified.

333. The findings in the 2016 CDC Guideline both confirmed the existing body of scientific evidence regarding the questionable efficacy of opioid use and contradicted Defendants' statements about opioids.

334. For instance, the Guideline states "[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)" and that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder." The Guideline further confirms there are significant symptoms related to opioid withdrawal, including drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction. These findings contradict statements made by Defendants regarding the minimal risks associated with opioid use, including that the risk of addiction from chronic opioid use is low.

335. The Guideline also concludes that there is "[n]o evidence" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain . . ." Furthermore, the Guideline indicates that "continuing opioid therapy for 3 months substantially increases the risk of opioid use disorder." Indeed, the Guideline indicates that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit." These findings flatly contradict claims made by the Defendants that there are minimal or no adverse effects of long-term opioid use, or that long-term opioid use could actually improve or restore a patient's function.

336. In support of these statements about the lack of long-term benefits of opioid use, the CDC concluded that "[a]lthough opioids can reduce pain during short-term use, the clinical

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evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy." The CDC further found that "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

337. With respect to opioid dosing, the Guideline reports that "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." The CDC specifically explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that there is an "increased risk[] for opioid use disorder, respiratory depression, and death at higher dosages." As a result, the CDC advises doctors to "avoid increasing dosage" above 90 MME per day. These findings contradict statements made by Defendants that increasing dosage is safe and that under-treatment is the cause for certain patients' aberrant behavior.

338. The 2016 CDC Guideline also contradicts statements made by Defendants that there are reliable risk-mitigation tactics to reduce the risk of addiction. For instance, the Guideline indicates that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

339. Finally, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." In particular, the CDC found as follows:

> The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of

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> abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

Accordingly, the CDC's findings regarding "abuse-deterrent technologies" directly contradict Purdue and Endo's claims that their new pills deter or prevent abuse.

340. Notably, in addition to the findings made by the CDC in 2016, the Washington State Agency Medical Directors' Group (AMDG)—a collaboration among several Washington State Agencies—published its *Interagency Guideline on Prescribing Opioids for Pain* in 2015. The AMDG came to many of the same conclusions as the CDC did. For example, the AMDG found that "there is little evidence to support long term efficacy of [chronic opioid analgesic therapy, or "COAT"] in improving function and pain, [but] there is ample evidence of its risk for harm . . ."[195]

341. In addition, as discussed above, in contrast to Defendants' statements that the 1980 Porter and Jick letter provided evidence of the low risk of opioid addiction in pain patients, the NEJM recently published a letter largely debunking the use of the Porter and Jick letter as evidence for such a claim.[196] The researchers demonstrated how the Porter and Jick letter was irresponsibly cited and, in some cases, "grossly misrepresented," when in fact it did not provide evidence supporting the broad claim of low addiction risk for all patients prescribed opioids for pain. As noted above, Dr. Jick reviewed only files of patients administered opioids in a hospital setting, rather than patients sent home with a prescription for opioids to treat chronic pain.

342. The authors of the 2017 letter described their methodology as follows:

> We performed a bibliometric analysis of this [1980] correspondence from its publication until March 30, 2017. For each citation, two reviewers independently evaluated the portrayal of the article's conclusions, using an adaptation of an established taxonomy of citation behavior along with other aspects of generalizability . . . For context, we also ascertained the number of citations of

[195] *Interagency Guideline on Prescribing Opioids for Pain*, Agency Med. Directors' Group (June 2015), http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf.

[196] Leung, et al., *supra* note 113.

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> other stand-alone letters that were published in nine contemporaneous issues of the *Journal* (in the index issue and in the four issues that preceded and followed it).
>
> We identified 608 citations of the index publication and noted a sizable increase after the introduction of OxyContin (a long-acting formulation of oxycodone) in 1995 . . . **Of the articles that included a reference to the 1980 letter, the authors of 439 (72.2%) cited it as evidence that addiction was rare in patients treated with opioids. Of the 608 articles, the authors of 491 articles (80.8%) did not note that the patients who were described in the letter were hospitalized at the time they received the prescription, whereas some authors grossly misrepresented the conclusions of the letter** . . . Of note, affirmational citations have become much less common in recent years. In contrast to the 1980 correspondence, 11 stand-alone letters that were published contemporaneously by the Journal were cited a median of 11 times.[197] (Emphasis added).

343. The researchers provided examples of quotes from articles citing the 1980 letter, and noted several shortcomings and inaccuracies with the quotations. For instance, the researchers concluded that these quotations (i) "overstate[] conclusions of the index publication," (ii) do[] not accurately specify its study population," and (iii) did not adequately address "[l]imitizations to generalizability."[198]

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[197] *Id.* (emphasis added).

[198] Supplementary Appendix to Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/suppl/10.1056/NEJMc1700150/suppl_file/nejmc1700150_appendix.pdf.

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Quote	Reference	Comment
"This pain population with no abuse history is literally at no risk for addiction."	Kowal N. What is the issue?: pseudoaddiction or undertreatment of pain. Nurs Econ 1998;17(6):348–9	
"In truth, however, the medical evidence overwhelmingly indicates that properly administered opioid therapy rarely if ever results in "accidental addiction" or "opioid abuse"."	Libby RT. Treating Doctors as Drug Dealers: The Drug Enforcement Administration's War on Prescription Painkillers. The Independent Review 2006;10(4):511-545.	
"Fear of addiction may lead to reluctance by the physician to prescribe. [...] However, there is no evidence that this occurs when prescribing opioids for pain."	Iles S, Catterall JR, Hanks G. Use of opioid analgesics in a patient with chronic abdominal pain. Int J Clin Pract 2002;56(3):227–8.	
"In reality, medical opioid addiction is very rare. In Porter and Jick's study on patients treated with narcotics, only four of the 11,882 cases showed psychological dependency."	Liu W, Xie S, Yue L, et al. Investigation and analysis of oncologists' knowledge of morphine usage in cancer pain treatment. Onco Targets Ther 2014;7:729–37.	Overstates conclusions of the index publication does not accurately specify its study population. Limitations to generalizability are not otherwise explicitly mentioned.
"Physicians are frequently concerned about the potential for addiction when prescribing opiates; however, there have been studies suggesting that addiction rarely evolves in the setting of painful conditions."	Curtis LA, Morrell TD, Todd KH. Pain Management in the Emergency Department 2006;8(7).	
"Although medicine generally regards anecdotal information with disdain (rigorously controlled double-blind clinical trials are the "gold standard"), solid data on the low risk of addiction to opioid analgesics and the manageability of adverse side effects have been ignored or discounted in favor of the anecdotal, the scientifically unsupported, and the clearly fallacious."	Rich BA. Prioritizing pain management in patient care. Has the time come for a new approach. Postgrad Med 2001;110(3):15–7.	
"The Boston Drug Surveillance Program reviewed the charts of nearly 12,000 cancer pain patients treated over a decade and found only four of them could be labeled as addicts."	Levy MH. Pharmacologic management of cancer pain. Semin Oncol 1994;21(6):718–39.	Incorrectly identifies the index study population as cancer patients; does not otherwise address limitations to generalizability.

344. Based on this review, the researchers concluded as follows:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy. In 2007, the manufacturer of OxyContin and three senior executives pleaded guilty to federal criminal charges that they misled regulators, doctors, and patients about the risk of addiction associated with the drug. Our findings highlight the potential consequences of inaccurate citation and underscore the need for diligence when citing previously published studies.[199]

[199] Leung, et al., *supra* note 113.

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345. These researchers' careful analysis demonstrates the falsity of Defendants' claim that this 1980 letter was evidence of a low risk of addiction in opioid-treated patients. By casting this letter as evidence of low risk of addiction, Defendants played fast and loose with the truth, with blatant disregard for the consequences of their misrepresentations.

G. The Opioid Epidemic Has Directly Affected Skagit County and the Cities

346. Skagit County, located in northern Washington State, is sixty miles north of Seattle and fifty-five miles south of the Canadian border. Skagit County has over 123,000 residents, and 1,000,000 acres of land.[200] Residents of Skagit County are spread out among eight cities, numerous small towns, and rural communities. The Cities of Mount Vernon, Sedro-Woolley, and Burlington are in Skagit County.

347. Much like the rest of the United States, Skagit County is facing crisis levels of opioid use and abuse. Skagit County had a 41.6% increase in opioid-related deaths between 2002-2004 and 2011-2013.

348. As noted above, the rate of opioid-related deaths in Skagit County is higher than the average for Washington State, with 11.2 deaths per 100,000 residents compared to a state average of 9.6.[201]

349. More than one quarter of the entire Skagit population (26.64%) was prescribed an opioid in 2014. That year, 125,436 opioid prescriptions were dispensed to 31,839 Skagit residents.[202] Given that the Skagit County population was approximately 119,500 at the time, doctors wrote more opioid prescriptions than there were residents in the County.

350. As is true around the country, the rise of prescription opioids in Skagit County was followed closely by a dramatic rise in heroin use. Aggressive promotion of prescription opioids broadened the market for all opioids. For many, heroin replaced prescription opioids when they could no longer obtain prescriptions for OxyContin or other prescription opioids.

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[200] Skagit County Trends, http://www.skagitcountytrends.ewu.edu/ (last visited May 22, 2018).

[201] *Opioid-related Deaths in Washington State, 2006-2016, supra* note 8.

[202] *Population and Total Controlled Substances Prescriptions, Skagit County, CY 2014, supra* note 10.

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Over half of heroin users in Skagit County report that they were hooked on a prescription opioid before trying heroin.[203]

351. In 2015, 530 Skagit County residents received substance use disorder treatment with heroin dependence listed as their primary concern upon admission.[204] This was 35% of all treatment admissions in Skagit County, although heroin treatment makes up only 26% of treatment statewide. Heroin detox admissions to treatment programs in Skagit County are rising close to the level of admissions for alcohol, which has historically been the highest.[205]

352. The rise in opioid addiction is also reflected in the rates at which people receive medication for opioid dependence. Skagit County has the highest distribution rate of buprenorphine in Washington State.[206]

353. Buprenorphine, distributed under the brand name Suboxone among others, is a medication approved by the FDA for treatment of opioid dependence. Not only is the buprenorphine distribution rate highest in Skagit County, but it is increasing. According to the University of Washington's Alcohol & Drug Abuse Institute (ADAI), between 2002 and 2004, there were 125.2 Skagit County residents per 100,000 who received buprenorphine. By the next data set (2011-2013), the rate of distribution increased by 367.4%, to 585.8 persons per 100,000.[207]

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[203] *Opioid Workgroup Leadership Team 2016 Summary Report and Recommendations*, Skagit County Population Health Trust Advisory Committee (2016), https://www.skagitcounty.net/PHTAC/Documents/Opioid%20%20Report%20%20020317.pdf.

[204] *Id.*, citing Washington State Department of Social and Health Services, Division of Behavioral Health and Recovery, System for Communicating Outcomes, Performance and Evaluation (SCOPE-WA).

[205] *Id.*

[206] *Id.*

[207] *Opioid Trends Across Washington State*, University of Washington Alcohol and Drug Abuse Institute (Apr. 2015), http://adai.uw.edu/pubs/infobriefs/ADAI-IB-2015-01.pdf.

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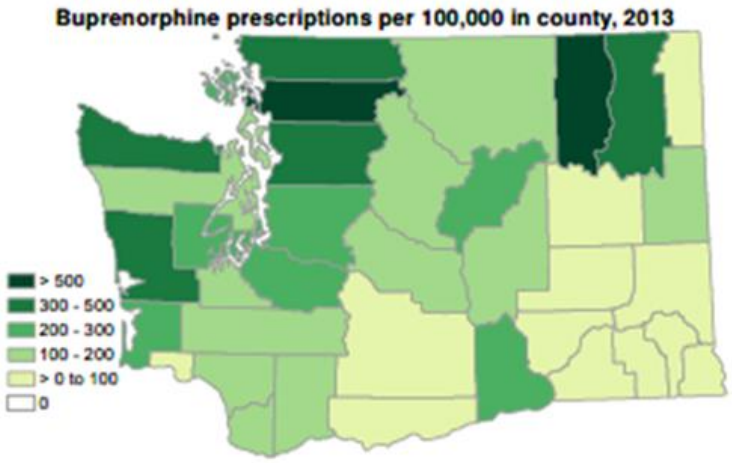

354. Another indicator of the extent of opioid abuse in Skagit County is the number of needles collected at needle-exchange sites. In just four months of 2016, over 250,000 needles were collected at eight sites in Skagit County, according to data from Phoenix Recovery Services, a substance abuse treatment center that has served the residents of Skagit County since 1999.

355. In 2015, over half (55%) of needle-exchange clients in Skagit County reported witnessing an overdose in the previous year.[208] And of the Skagit County respondents to the 2015 Naloxone Distribution and Refill survey, 68% reported witnessing an overdose, while 13% had personally overdosed in the last twelve months.[209]

356. The opioid epidemic is not limited to adults. According to a 2014 survey, 5% of tenth graders in Skagit County said they had used a painkiller to "get high" in the preceding month before the survey was conducted.[210] In addition, the percent of tenth graders who reported having ever used heroin in their lifetimes was higher in Skagit County than in Washington State overall.[211]

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[208] *Id.*
[209] *Id.*
[210] *Id.*
[211] *Id.*

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357. As these numbers illustrate, Skagit County has been hard hit by the opioid epidemic.

1. A network of public and private organizations is working to combat the opioid epidemic in Skagit County.

358. Numerous entities, both public and private, have been fighting the opioid epidemic in Skagit County. The work of these organizations, including needle exchange and drug take-back programs, reflects the extent of the opioid epidemic in Skagit County.

359. Skagit County has eighteen agencies, ranging from school to hospitals, the criminal justice system to non-profits, offering over forty programs for intervention, education, assessment, funding, shelter, case management, emergency care, and supervision.

360. Many of these programs—including Opioid Outreach, the Medication Assisted Treatment Clinic, and the RISE Mobile Needle Exchange, described in further detail below—are programs that deal directly and entirely with individuals dealing with opioid use disorders. In other words, these programs devote 100% of their purpose and existence to providing services related to opioid use. Other programs deal with substance use disorders generally, including opioid use.

361. There are also twelve treatment, advocacy, and support organizations providing treatment in Skagit County: Narcotics Anonymous, Brigid Collins, Catholic Community Services-Access to Recovery Programs, Christ-the-King Celebrate Recovery, NAMI Skagit, New Earth Recovery, North Sound Recovery Coalition, OHANA, Oxford Homes, Pioneer Transitions House, REACH Center, and SMART Recovery programs.

362. The Referral Intervention Safety Education (RISE) Mobile Needle Exchange program began in April 2015, funded by the Skagit County Public Health and Community Services Department and offered by Phoenix Recovery Services. Previously, the Washington State Department of Health funded a needle exchange program, but that ended in 2012 due to budget cuts. In its first three weeks, the RISE Mobile Needle Exchange collected 850 needles in

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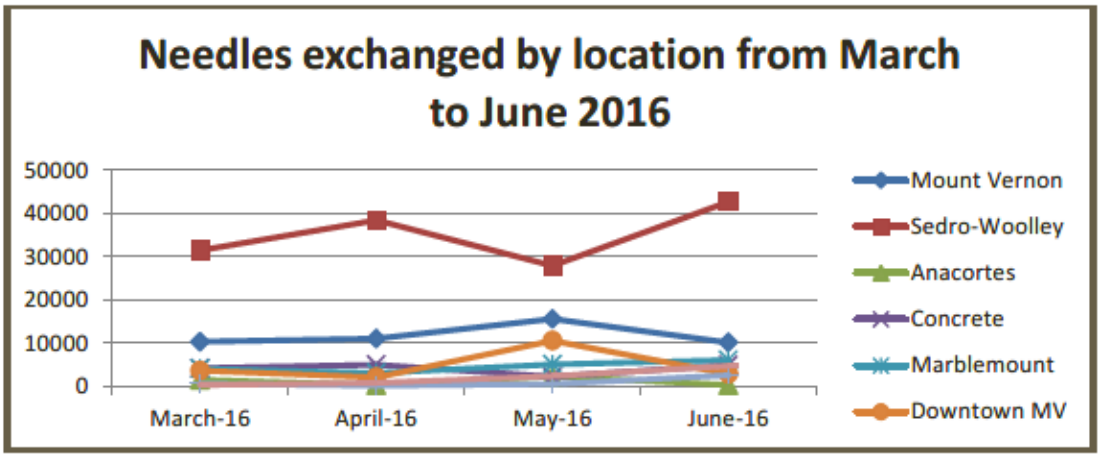
Mount Vernon and 3,430 needles in Sedro-Woolley. In addition to the 1:1 exchange of used needles for clean needles, the RISE program offers safe disposal containers, equipment, counseling, and referral, and naloxone overdose reversal kits are available on the bus.

363. As the RISE program has become more established, the volume of needles exchanged has grown. Between March and June 2016, 538 people exchanged 255,560 needles across eight sites in Skagit County.[212]



364. As a result of the needle-exchange services there were eighty confirmed overdose reversals or a life saved every 2.4 days. Mount Vernon and Sedro-Woolley were the sites with the highest utilization, at 222 and 242 individuals, respectively.

365. Skagit County also has five secure drug take-back locations. These drug take-back sites, located at law enforcement offices, provide safe disposal of prescription pain medication and get unused drugs out of circulation. This service is critical given the nature of the opioid crisis and Defendants' success in bringing about rampant overprescribing of their narcotics, such that many people receive, for example, a thirty-day prescription of opioids when two days' worth of pain relief would have been sufficient. The excess pills find their way to other users and even the water supply.[213]

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[212] *Id.*

[213] In fact, the County's Public Works department has found needles at several of its sampling locations.

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366. Medication Assisted Treatment (MAT) is widely used throughout the County. Between 2002 and 2004 there were 125.2 residents per 100,000 who received buprenorphine. That rate of distribution increased by 367.4% (from 2011-2013) to 585.8 persons per 100,000. A new MAT facility, Ideal Option, opened in April 2016 in Mount Vernon, which serves over 200 patients.

367. The use of Narcan by the following Skagit County organizations contributes most to preventing overdose deaths: County EMS Services, Anacortes Police, Sedro-Woolley Police Department, Swinomish Police, the East County Sheriff, Skagit Regional Health Emergency Department, and RISE Mobile Needle Exchange.

368. In 2015, Skagit County convened an Opioid Workgroup to analyze, collaborate, and ultimately solidify a team of community leaders dedicated to taking steps to address the opioid epidemic and related public health crisis. The Opioid Workgroup was commissioned by the Skagit County Population Health Trust Advisory Committee (PHT), which was appointed by the Skagit County Board of Health and serves as a Health Advisory Committee which identifies local health priorities.

369. The PHT's community assessment included conducting five community listening sessions in which nearly 200 participants provided feedback on the assessment data and priorities. These sessions made it clear that opioid misuse and abuse was an emergent and critical issue in Skagit County.

370. In December 2016, members of the Opioid Workgroup Leadership Team presented their findings and plan to the Skagit County Board of Health. Skagit County subsequently released its Opioid Workgroup Leadership Team 2016 Summary Report and Recommendations. The Workgroup Leadership Team analyzed data and local responses to the crisis and made recommendation plans for improvement. The recommended actions fall into the following categories: (1) prevent opioid misuse and abuse; (2) treat opioid abuse and

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dependence; (3) prevent deaths from overdose; and (4) use data to detect opioid misuse and abuse, monitor morbidity and mortality, and evaluate interventions.[214]

371. To prevent misuse of opioids in the community, particularly among youth, the Workgroup recommended, *inter alia*, convening take-back programs and supporting the statewide efforts to create a statewide drug take-back program, creating community-wide awareness and training aimed at reducing stigma. To treat opioid dependence, the Workgroup recommended improving the transition between types and levels of care, and linking those leaving the emergency department to treatment options. To advance the third goal of expanding access to and utilization of MAT, the Workgroup also recommended increasing the capacity of outpatient treatment programs, documenting and monitoring the wait times for stabilization at crisis beds, and expanding access to and utilization of MAT in the criminal justice system. And to prevent death from overdose, the Workgroup recommended ensuring first responders and all law enforcement have training on overdose response, and increasing the number of responders who carry naloxone.

372. The Opioid Workgroup's recommended actions, if fully implemented, are likely to meaningfully combat the opioid epidemic by saving lives now, treating those who suffer from opioid use disorder, and preventing future addictions. The recommended actions, however, are not cheap. Providing sufficient opioid treatment programs to serve the entire County, for example, will cost a significant amount of money for years to come.

373. On October 25, 2017, more than 150 stakeholders convened at the 2017 North Sound Opioid Summit with the goal of expanding the collective efforts to reverse the progression of the opioid epidemic across the North Sound Region. Representatives from law enforcement agencies, drug courts, treatment agencies, primary health care providers, county public health and human services departments, and elected officials and tribal partners convened to learn about local efforts and build new partnerships to develop ways to combat the opioid crisis.

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[214] *Opioid Workgroup Leadership Team 2016 Summary Report and Recommendations, supra* note 203.

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374. The Summit recommendations include: (a) expanding "upstream" efforts, i.e. working closely with schools and youth service organizations to expand evidence-based prevention and increase funding to expand access to naloxone for people at risk; (b) increasing community support and the availability of MAT; (c) providing MAT to persons who are incarcerated or being released from jail; (d) expanding syringe exchange programs; (e) creating housing opportunities for persons who are receiving MAT; (f) continuing to address the stigma around opioid use disorder; (g) supporting local efforts to address the opioid crisis as a Public Health problem; and (h) expanding recovery supports.

375. In addition, in June 2017, the Washington Attorney General's Office hosted the Summit on Reducing the Supply of Illegal Opioids in Washington, which brought together law enforcement, public health experts, prosecutors, and medical professionals to identify next steps and solutions to addressing this epidemic.

376. Skagit County Prosecuting Attorney Rich Weyrich—in his role as President of the Washington Association of Prosecuting Attorneys—was one of three co-signers of a report issued following the summit that set out specific goals and recommendations reduce the supply of illegal opioids, prevent opioid addiction, and connect those suffering from addiction to treatment. The other co-signers of the report were Washington Attorney General Bob Ferguson and Chief John Batiste of the Washington State Patrol.[215]

2. The opioid epidemic has contributed significantly to the homelessness crisis in Skagit County.

377. As opioid misuse and abuse has increased in Skagit County, so too has homelessness. While the causes of homelessness are multi-faceted and complex, opioid abuse is both a contributing cause and a result of homelessness.

[215] *Reducing the Supply of Illegal Opioids in Washington State* (Nov. 2017), http://agportal-s3bucket.s3.amazonaws.com/uploadedfiles/Another/News/Press_Releases/OpioidSummitReport.pdf

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378. Survey data indicate that opioid use and homelessness are linked in Skagit County. In 2015, 40% of the RISE Mobile Needle Exchange clients in Skagit County reported living in temporary or unstable housing, and 37% reported being homeless.[216] Compared to the statewide average, Skagit's percentage of respondents in permanent housing was 16% lower. As the Skagit Workgroup noted, "stable housing is a critical need for stabilization and recovery."[217]

379. Prescription opioids have not only helped to fuel homelessness, but have also made it immeasurably more difficult for Plaintiffs to address. For example, mental health services are critical for many in the homeless population, but opioid use and addiction can make it more difficult to provide effective mental health treatment. Opioids provide a way to self-medicate and avoid getting the treatment that might lead to long-term success and more positive outcomes. Whether opioid addiction was a contributing cause or a result of homelessness, opioid addictions now prevent many individuals from regaining permanent housing.

380. Additionally, while the leading cause of death among homeless Americans used to be HIV, it is now drug overdose. A study published in JAMA Internal Medicine found that overdoses were the leading cause of death among individuals experiencing homelessness in the Boston area. Of the overdose deaths, 81% involved opioids.[218]

H. Plaintiffs Have Borne the Financial Burden of Defendants' Conduct

381. As a direct result of Defendants' conduct described herein, Plaintiffs suffered significant and ongoing harms—harms that will continue well into the future. Each day that Defendants continue to evade responsibility for the epidemic they caused, the County and the Cities must continue allocating substantial resources to address it.

382. The harms caused by Defendants impact Plaintiffs in various ways. The statistics shared above provide a glimpse of the devastating toll the opioid crisis has taken on Skagit

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[216] *Id.*

[217] *Id.*

[218] Travis P. Baggett, MD, MPH, Stephen W. Hwang, MD, MPH, James J. O'Connell, MD, et al., *Mortality Among Homeless Adults in Boston, Shifts in Causes of Death Over a 15-Year Period*, 173 (3) JAMA Intern Med. 189-95 (2013), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1556797#qundefined.

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County and the Cities. Responding to the consequences of the epidemic, and taking steps to slowly and eventually end it, are high priorities for Plaintiffs. But doing so requires Plaintiffs to shoulder a massive economic burden and allocate significant resources to their various departments.

383. Skagit County and the Cities are served by an array of different departments, agencies, and offices, which provide essential services to their residents. While each of these departments, agencies, and offices feel the impact of the opioid crisis in some form, there are certain departments in particular that have borne the economic and financial brunt of the epidemic caused by Defendants' conduct. Plaintiffs have had to invest significant resources in addiction programs and other human services, which are widely used by residents of Skagit County and the Cities. Put simply, the effects of the opioid epidemic impose human and financial costs at all levels.

384. As explained in further detail below, costs for these departments and the various divisions and agencies within the departments have dramatically increased due to the opioid crisis. Defendants' conduct has forced Plaintiffs to incur substantial costs they otherwise would not have incurred, and will require Plaintiffs to spend resources in the future to deal with lasting and ongoing harms.

385. Plaintiffs' costs from rendering public services are recoverable pursuant to the causes of actions raised by Skagit County and the Cities. Defendants' actions alleged herein are not isolated incidents, but instead part of a sophisticated and complex marketing scheme carried out over the course of more than twenty years. Their actions have caused a substantial and long-term burden on the public services provided by Skagit County and the Cities. In addition, the public nuisance created by Defendants, and Plaintiffs' requested relief in seeking abatement of that nuisance, further compels Defendants to reimburse and compensate Plaintiffs for costs they incurred in addressing the crisis Defendants caused.

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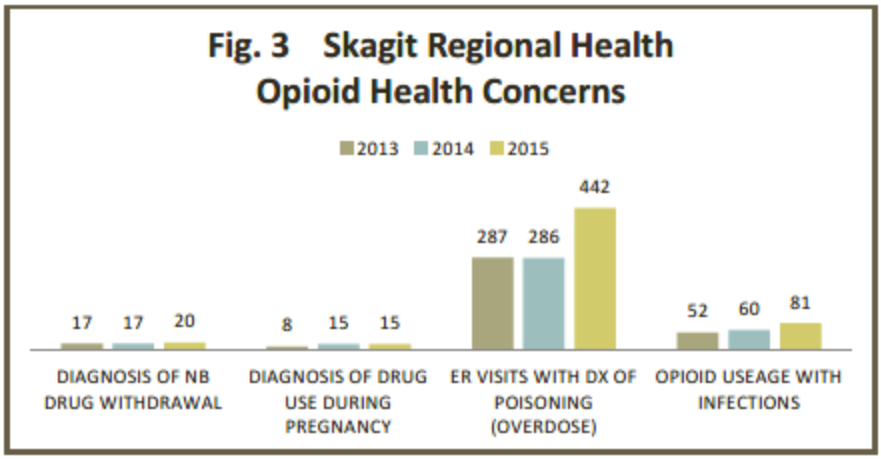
1. Plaintiff Skagit County faces enormous burdens as a result of Defendants' Conduct.

a. Emergency medical services confront the consequences of the opioid crisis daily.

386. Skagit Regional Health, the third largest public district hospital in Washington, experienced a 155% increase in emergency rooms visits for overdoses between 2014 and 2015.[219]



387. However, overdose statistics do not reflect all individuals seeking emergency treatment for opioid use disorder. Due to complexities in coding within the emergency department, a visit is coded by the presenting issue and not necessarily by the underlying issue. For example, a primary admit for an abscess at an injection site would be coded as "wound care" rather than the secondary "substance abuse disorder" causing the abscess.[220]

388. According to 9-1-1 call center data for Skagit County, between August 1, 2015, and January 31, 2016, the County's Emergency Management System services were dispatched thirty-three times each month for drug-related incidents in Skagit County. Narcan (naloxone) saved a life every 4.5 days through EMS alone.[221] Naloxone is an antagonist that blocks opioid

[219] *Opioid Workgroup Leadership Team 2016 Summary Report and Recommendations, supra* note 203
[220] *Id.*
[221] *Id.*

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receptors in the nervous system and acts to reverse the effects of most opioids. Narcan is the brand name for the only FDA-approved naloxone nasal spray.

389. Skagit County EMS also trains responders for the Burlington Fire Department and provides them with naloxone.

390. Responding to opioid overdoses is expensive; it involves sending ambulances and specially trained staff to the emergency. People who have overdosed on opioids typically require at least one, if not several, doses of naloxone, each of which carries a significant price tag. Then the patient must be transported to the emergency room. The costs of materials, maintenance, medication, and staff time are enormous.

391. And, of course, time, materials, and money spent addressing opioid overdoses means fewer resources and less time to respond to other medical emergencies.

b. The Skagit County Sheriff's Office has incurred substantial costs in responding to the epidemic caused by Defendants.

392. The impact of the opioid epidemic on the Sheriff's Office has also been profound. The street market for opioids—both prescription and non-prescription—has dramatically expanded in the County over the past decade. Crimes associated with illicit drug use, including violent and property crimes, have grown significantly. And the number of people involved in drug-related activities has reached new levels.

393. The opioid epidemic in Skagit County has followed similar trends as elsewhere in the state. The Sheriff's Office has found that over the past five years, there has been a sharp increase in the use and abuse of heroin and prescription opioids in Skagit County. In the 1990s, opioids were nearly nonexistent among illicit drug use in the County. Today, that has changed, and opioids dominate the street market for drugs in the County. Not only have opioids taken over the drug market, they have increased the overall volume of the drug trade in the County, with respect to both the number of people and the amount of drugs involved.

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394. All of this opioid-related activity has put serious strains on resources at the Sheriff's Office. The kinds of resources the Sheriff's Office devotes to its response to the opioid crisis are illustrated in three units in the department.

395. First, the Inter-Local Drug Unit is tasked with addressing drug-related cases. This unit is busy, and uses significant resources from the department. The Inter-Local Drug Unit, for example, has a full-time detective, and the Sheriff has assigned one of his chief deputies as the commander of this unit. And, this unit takes up at least 10% of the department's evidence clerk's time processing and assessing evidence for the unit.

396. Second, the Proactive Unit devotes at least 90% of its work to dealing with drug-related issues. The Proactive Unit often responds to cases involving drug users or property crimes associated with drug use. Two deputies are devoted to this unit and a sergeant spends at least 30% of his time working with this unit.

397. Third, the High Risk Team, or "SWAT" Team, is used to deal with high-risk offenders. Almost every time the SWAT Team is called out, the case involves drugs.[222] Ten deputies are assigned to this team. And the costs of maintaining, training, and deploying the SWAT Team are significant.

398. In addition, the K-9 Unit provides patrol dogs that aid law enforcement personnel in the search, location, and apprehension of individuals as well as the search for evidence of crimes. K-9 dogs are cross-trained to track humans and search for the odor of drugs. K-9s train regularly in narcotics detection.

399. Skagit County also has a Drug Task Force or "vice" unit made up of law enforcement officers from a variety of law enforcement agencies including the Skagit County Sheriff's Office. The Drug Task Force is responsible for gathering intelligence on illegal narcotics activity through Skagit County and making arrests and seizures based on that

[222] Notably, Washington has legalized marijuana, and marijuana-possession crimes are not prosecuted, with the exception of minors in possession.

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intelligence. The Drug Task Force works closely with federal and local agencies sharing and acting on information to shut down drug houses, intercept deliveries, and bring high-profile drug-related criminals to justice in Skagit County.

c. Defendants' misrepresentations have had a profound impact on the County's criminal justice system.

341. The rise in opioid-related crimes also burdens the criminal justice system in the County. These burdens are illustrated by the impacts on the County jail, the Skagit County Public Defender's Office, and the Office of Assigned Counsel ("OAC").

(i) County jail

400. For instance, the County's jail in Mount Vernon houses inmates suffering from opioid withdrawal—individuals who require maximum attention from jail staff. Within twenty-four hours of being detained, these individuals begin experiencing withdrawal symptoms and become extremely ill, requiring the County's jail medical staff to provide Ondasetron for nausea/vomiting, Loperamide for diarrhea, ibuprofen/Tylenol for body aches, and Gatorade for hydration. The County estimates the annual cost of treating inmates for these symptoms of opioid withdrawal alone is approximately $24,000.

401. When these symptoms cannot be controlled, the County jail must transport these individuals to a local hospital. Each utilization of an ambulance for transport and the corresponding emergency room visit comes at a cost of approximately $2,500 per event. On average, the County jail transports four to six individuals per month under these circumstances, leading to a minimum and approximate cost of $120,000 on an annual basis just for this piece of care.

402. Furthermore, the County estimates that its medical staff at its jails spends at least 50% of their time dealing with opioid withdrawal patients and their symptoms. Based on a minimal staffing model for these clinical services, the amount of money spent on staffing for

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these duties is over $300,000 per year. And due to the increasing number of inmates and detained individuals who are addicted to opioids, the costs will likewise increase in the future.

(ii) Skagit County Public Defender's Office

403. Over the last twenty years, the Skagit County Public Defender's Office has seen a significant increase in the number of drug-related charges it handles, including opioid-related cases, which comprise a large portion of the Public Defender's Office's drug-related cases.

404. The Public Defender's Office also handles approximately 130% more felony cases than it did twenty years ago, and approximately 40% of the Office's current felony cases involve drug possession, delivery of drugs, or possession with intent to deliver drugs.

405. Historically, the Public Defender's Office represented very few clients who used opioids, whereas today that is the norm. The crimes these clients are charged with are not necessarily drug-related charges, but may include other offenses for conduct driven by opioid addiction and the cost to maintain a habit, such as burglary, possession of stolen property, theft, forgery, trafficking in stolen property, and malicious mischief. In addition, crimes against persons, traffic-related offenses, and dependency cases involving drug-affected parents have all increased in recent years.

406. The increase in opioid-related crimes has had a dramatic impact on the number of cases the Public Defender's Office handles and the cost to operate it. Significant resources are invested in handling cases with drug involvement, including work by attorneys, legal assistants, investigators, and transcriptionists.

(iii) Office of Assigned Counsel

407. The opioid crisis has also wrought significant changes on the Office of Assigned Counsel ("OAC"). Among other things, OAC performs eligibility screening for indigent defense services for Skagit County Superior and District Court and determines whether individuals are "indigent" pursuant to RCW 10.101.

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408. OAC has reported a marked increase over the past ten to fifteen years in the number of people it screens who are addicted to heroin and prescription opioids. Just twenty or twenty-five years ago, OAC had a handful of heroin-using clients, most of whom were functioning older adults who were able to maintain their jobs even while using opioids. In stark contrast, today OAC sees generational drug-addicted families and a much younger generation of individuals addicted to opioids, including pregnant mothers and babies who are born addicted to heroin.

409. The number of opioid-addicted clients, and the changing demographics of those addicted to opioids, has increased OAC's caseload, putting new strains on its resources. The screening process for addicted clients takes longer due to potential physical health, mental health, and homelessness issues. Once the client is processed in OAC's system, OAC helps provide them with medical and mental health services. For in-custody individuals who need help with these services, OAC sends referrals to help them get services for their medical and health needs while they are in custody. OAC also receives an increase in contacts from family members who have never been involved in the criminal justice system who are now experiencing it firsthand because of a family member who is opioid-addicted and incarcerated. OAC reported that these individuals "feel lost and confused trying to seek help for their addicted family members" and they do not understand the criminal justice system process.

410. Because OAC works directly with these individuals on a daily basis, it sees the personal toll of the epidemic on County residents. OAC has worked with people who have battled their addictions and won. But, far too often, people are unable to beat their addictions—which often began with a prescription from a trusted doctor. Many of OAC's clients who have become addicted to opioids end up being repeat offenders, spending their lives in and out of custody, and relying on OAC's critical services.

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411. With larger client lists to serve, and clients who require significantly more resources and time, OAC has had to increase its budget—hiring new attorneys, investigators, social workers, and other staff to meet its growing needs.

a. Defendants' conduct has dramatically increased Skagit County's health care costs.

412. Defendants' misrepresentations regarding the purported safety and efficacy of opioids have also substantially increased the County's health care costs. Skagit County provides health insurance to its employees and their beneficiaries. The County is self-insured, which means among other things that when anyone covered by the County's health insurance program visits a doctor or fills a prescription or otherwise incurs covered health-related costs—including, for example, opioid-related medical claims—the County pays a substantial portion of those costs directly.

413. Skagit County provides health insurance to over 650 employees and 940 dependents, and therefore insures nearly 1,600 individuals. In connection with this coverage, the County has spent significant amounts of money on prescription opioids. For example, in 2017 alone, the County spent more than $12,000 on prescription opioids, including those manufactured by Defendants.

414. The direct costs of filling opioid prescriptions are just a small part of the total cost to the County for prescriptions of opioids. The County also pays for medical claims related to opioids, including under its workers' compensation plan. In other words, any time an individual covered by the County's health insurance program submits a claim for treatment and the primary diagnosis is opioid-related—including for instance, treatment for opioid addiction—the County incurs costs in providing coverage. Had Defendants told the truth about the risks and benefits of opioids, Skagit County would not have had to pay for these drugs or the costs related to their prescription.

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415. Even for those people covered by the County who do not get addicted, improperly prescribed opioids carry other costs for the County. For example, when patients receive opioid prescriptions for chronic pain, they often fail to take other steps to address the root causes of that pain. Thus, even if patients are able to wean themselves off of opioids, the underlying conditions often remain, and may have become worse or more difficult and expensive to treat.

416. Across the United States, people who are prescribed opioid painkillers cost health insurers approximately $16,000 more than those who do not have such prescriptions.[223] Those costs, including those borne by the County, would have been avoided had Defendants not hidden the truth about the risks and benefits of opioids.

417. Furthermore, when County employees are prescribed opioid painkillers for chronic pain they often are forced to miss work because the drugs' effects interfere with the ability to work. Since opioid prescriptions fail to treat the cause of the pain, employees often continue to miss work due to the ongoing pain.

418. In fact, recent studies suggest that opioids actually slow recovery times, keeping employees out of work longer than they would have been had they not taken these unnecessary pharmaceuticals. If those employees become addicted to the opioids, they are likely to miss even more work. In fact, in some cases, the use of opioids for work-related injuries may actually increase the likelihood of receiving a disability determination. Studies suggest receiving more than a one-week supply of opioids or two or more opioid prescriptions soon after an injury doubles a worker's risk of disability at one-year post-injury, compared with workers who do not receive opioids.[224] Because of Defendants' misstatements, the County's employees have had losses in work time, which result in substantial losses to Skagit County.

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[223] *The Impact of the Opioid Crisis on the HealthCare System: A Study of Privately Billed Services*; FAIR HEALTH (Sept. 2016) http://www.khi.org/assets/uploads/news/14560/the_impact_of_the_opioid_crisis.pdf.

[224] Franklin, et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, *supra* note 193.

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419. Collectively, the annual cost to the County for all the direct claims it must pay for and the loss in productivity in connection with opioids and opioid-related claims totals more than $150,000 per year.

b. Defendants' conduct has affected the Solid Waste Division.

420. Skagit County's Solid Waste Division has not escaped the impacts of the opioid epidemic. Its staff deals with the fallout of the crisis on a daily basis, and the division has shifted significant resources to address the ongoing effects of the epidemic.

421. The waste associated with the opioid epidemic—needles and other drug paraphernalia—has presented the Solid Waste Division with significant challenges. For example, the Litter Crew Supervisor and his crew routinely find used needles alongside the roads they are tasked with keeping clean. To deal with this new danger, the division now must provide the cleanup team with training and equipment to keep them safe while dealing with this potentially hazardous material.

422. Also, homeless camps are becoming increasingly common throughout the County. As discussed above, while the causes of homelessness are multi-faceted and complex, the opioid crisis is contributing to a rise in homelessness and making the issue more intractable. As a result of the increased homeless population in the County over the past few years, the Solid Waste Division has had to shift significant resources into finding and cleaning homeless encampments. This is no small task. Often the camps are large, filled with needles, human waste, and garbage. It takes significant time to clean up these sites, and puts County workers in dangerous situations.

423. The number of vehicle camps—encampments where homeless people live in cars or RVs—has risen significantly throughout the County in the past few years. Vehicle camps provide particular challenges to the Solid Waste Division. The camps are often mobile, staying in one place for a few weeks at a time before moving on. While the camp may move, the waste created stays behind for the Solid Waste Division to clean up. It is critical for the Solid Waste

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Division to clean up the needles, other drug paraphernalia, and trash—all of which pose a threat to the public—at these sites, because the camps are typically in areas frequented by the public. Commuter park and rides, boat launches, and public parks are routinely used by vehicle campers.

424. The vehicle camps have increasingly required the Solid Waste Division to deal with abandoned cars and RVs. The division is responsible for cleaning up the abandoned vehicles before the County can remove the vehicle, impounding or taking it for demolition. In 2017, every abandoned vehicle to which the Solid Waste Division responded contained needles or other drug paraphernalia. And, while it was once rare for the County to respond to these types of abandoned vehicles, it has become a common demand on the Solid Waste Division's time and resources.[225]

c. The County's Parks and Recreation Department is also not immune to Defendants' conduct.

425. The County's Parks and Recreation Department has also had to deal directly with the opioid epidemic, including allocating significant resources to clean up discarded needles, patrol parks, respond to drug use in camp sites in east Skagit County, and to generally ensure the safety of the County's park visitors.

426. The need for clean-up of discarded needles in County parks, separate and apart from the clean-up performed by the County's Solid Waste Division, is substantial. During a three-month period in 2017, the vendor the County contracts with for this service collected more than 70,000 needles. The number of discarded needles directly affects County residents' ability to use and enjoy their parks—creating, for example, an environment where parents feel the need to inspect playgrounds and parks before letting their kids play.

[225] Relatedly, the County's Facilities Management Department has also had to deal with increasing costs related to clean-up of drug-related activities, monitoring homeless individuals and encampments for illegal and unsafe activity, and repairing and replacing damaged or vandalized county property and equipment.

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427. In a time where resources for parks are already slim in Washington State, the County has had to shift significant manpower to clean up its parks as a direct result of the opioid epidemic.

d. The Coroner's Office has also allocated substantial resources in responding to the crisis caused by Defendants.

428. The County's Coroner's Office has also incurred direct costs as a result of processing deaths associated with opioid overdose. From 2006 to present, the Coroner's Office attributes 155 deaths to opioid overdose, each one of which comes at a cost.

429. In particular, each autopsy costs the County $1,500, and as such, the County has spent $232,500 in processing deaths related to opioid overdoses alone.

e. Skagit County allocates significant resources to treatment centers and support services.

430. In the last ten years, the County has allocated nearly $6 million from taxes, grants, and federal, state, and local funds to operate, maintain, or otherwise sponsor the forty programs discussed above during this ten-year period.

431. The County's Public Health Department is heavily invested in addressing the epidemic caused by Defendants. For example, the County's Public Health Department funds the RISE Mobile Needle Exchange program run by Phoenix Recovery Services. With the growing prescription opioid and heroin crisis, there are rising concerns regarding disease transmission through shared needles, evidenced by parallel growth in Hepatitis C infections linked to rising injection drug use of prescription painkillers and heroin. Needle exchange programs not only protect against the spread of Hepatitis C and HIV but provide valuable services and provide a forum where people in recovery can seek treatment and connect with other individuals involved in treatment.

432. The County also operates a crisis center, which maintains a sixteen-bed crisis, mental health stabilization, and sub-acute detox program. Most of the services are available

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twenty-four hours a day, seven days a week. The Crisis Center also offers a seven-day Suboxone tapering program for opioid addiction, which is available for intake one day each week.

433. Skagit also has seven traditional treatment centers. These centers offer a full continuum of outpatient chemical dependency treatment services such as assessment, individual and group therapy which utilizes evidence-based practices.

434. There is a High Intensity Drug Trafficking Area (HIDTA) grant in place that funds Emergency Medical Services (EMS) to provide 100 Narcan kids to the Skagit County Sherriff's department and Anacortes Police Department.

2. The City of Mount Vernon is impacted by the crisis.

435. Like the rest of Skagit County, Mount Vernon has seen a dramatic increase in prescription opioid and heroin use. Furthermore, the city has also had to deal with Defendants' misconduct, including but not limited to the following directly affected departments: Parks and Recreation, Public Works, the Mount Vernon Library, the Fire Department, the Police Department, and the Municipal Prosecutor.

436. The Parks Division and the people who use Mount Vernon's lands are affected by the opioid crisis. The City of Mount Vernon has over 850 acres of park land and more than fourteen miles of city trails. Mount Vernon also has fourteen city parks. The Parks Division is tasked with providing facilities and maintaining parks and green spaces in the community.

437. The City of Mount Vernon Parks and Recreation Department expends resources to safely dispose of used needles and syringes. Exposure to such needles carries a risk of infection from blood borne pathogens (including HIV, Hepatitis B, and Hepatitis C). Encountering used syringes is a daily occurrence in most of Mount Vernon's city parks, especially within the Community Work Program. Needles are commonly found lying on the ground, along the fourteen miles of city trails, beneath bridges, and in city park bathrooms. It is also common to find blood splatter on the floors, walls, partitions, and fixtures from when users are purging the air out of the syringes prior to injection. Disposing of the syringes presents risks

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to employees, because of potential exposure to bloodborne pathogens through contaminated needles, sharps, or splash explosions, and training and equipping employees appropriately requires resources.

438. Needles are also found on the sidewalks and alleys in the Historic Downtown District with such frequency that the orientation of new participants in the Community Work Program now covers syringes and what to do when they are encountered.

439. Needles must be sorted separately from other trash and debris that the Parks and Recreation Department collects. Needles are placed in "sharps" containers, which are taken to the Solid Waste Division when full and placed into larger collection bins that are then removed by a third-party contractor. Sharps containers in three of their busier restrooms (located at Lions Park, Skagit Waterfront Park, and Edgewater Park) are checked daily and frequently emptied. Due to the special design of the receptacles, the containers within them are more expensive than standard containers.

440. The sharp increase in the homeless population in Skagit County is particularly visible in the City of Mount Vernon. The City of Mount Vernon created an interactive map containing data regarding unpermitted homeless encampments in the city.[226] The image below depicts the locations of homeless encampments in Mount Vernon with dots. Notably, the map below only illustrates approximately 60% of the encampments the city has on record. Mount Vernon is continuing to compile data on the growing homelessness issue in its city.

[226] Homeless Encampments, Mount Vernon http://mountvernonwa.maps.arcgis.com/apps/webappviewer/index.html?id=5c8cce772a134791940c02f69efb4c2f (last visited May 22, 2018).

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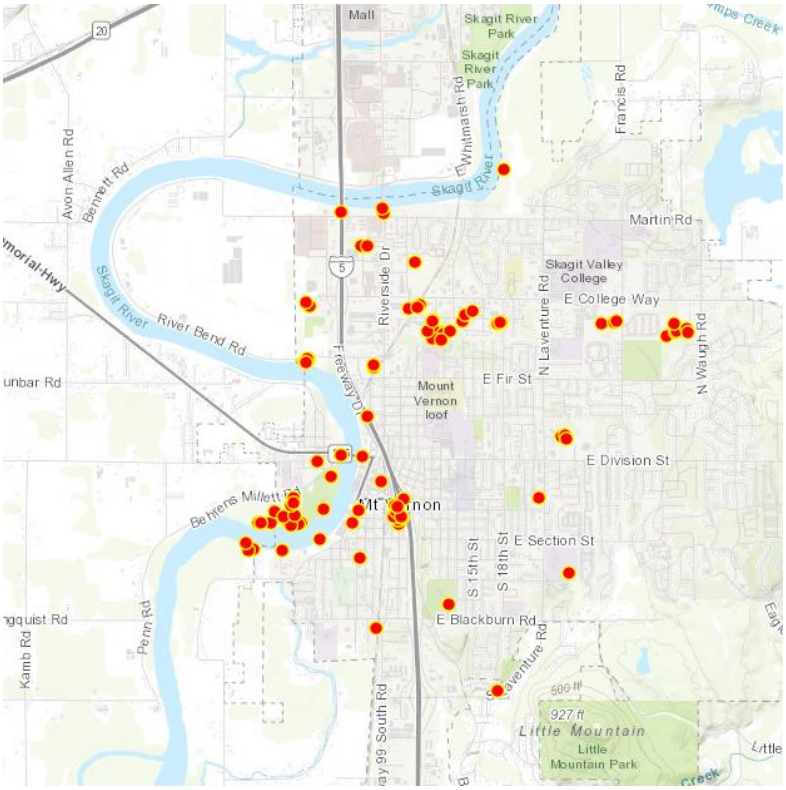

441. Syringes are often found at homeless encampments. The city reports that it is not uncommon to collect more than 100 used syringes lying around a camp, or tossed into the bushes near a camp. In one case, the Parks and Recreation Department recovered two large containers full of used needles. It was estimated that each container contained more than 1,000 needles. Annually, Mount Vernon collects more than 5,000 used syringes.

442. Used syringes at encampments present dangers to all who encounter them. A conservative estimate is that nine out of ten camps in the City of Mount Vernon have evidence of syringe use. City employees find syringes or the orange safety caps on syringes, which are commonly discarded. It is even less common to find syringe users resorting to other methods of safe disposal (such as plastic soda bottles).

443. Encampments are also contaminated with human and other wastes. Piles of human feces are frequently found in and around the camps.

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444. The below photo was taken at a homeless encampment located at Edgewater West in Mount Vernon.

445. Removing and cleaning encampments is labor intensive. Below is a photo of a city worker removing trash, needles, and human waste from a homeless encampment located behind the Coastal Derm in the City of Mount Vernon.

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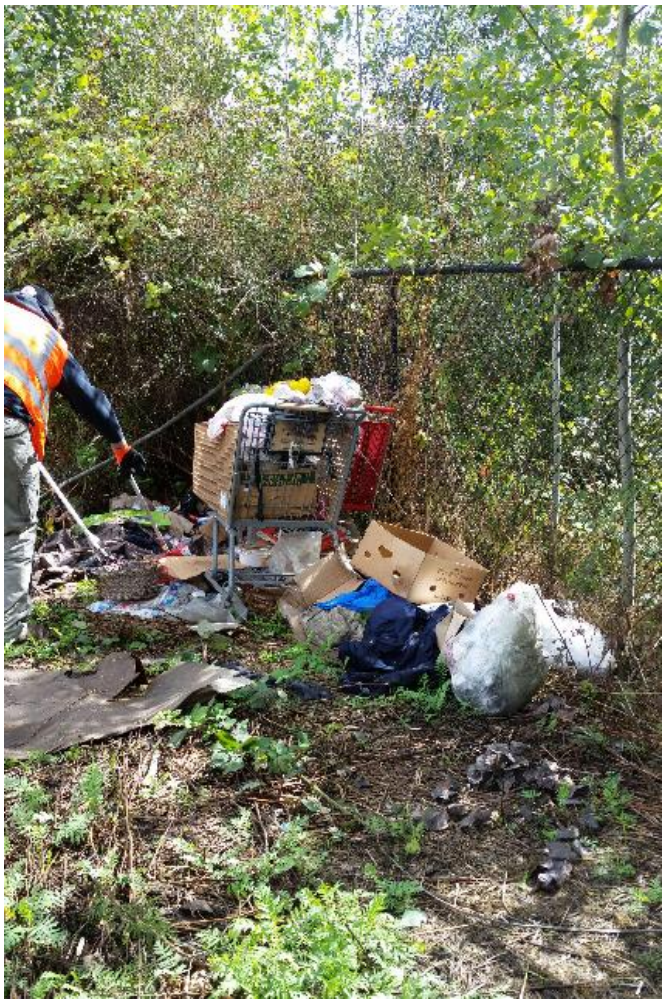

446. The Mount Vernon City Library expends resources to safely dispose of used needles and syringes found in the library. This includes resources spent on purchasing and installing sharps containers and staff time for clean-up. Twice in 2017, the library required plumber assistance to remove syringes from the library plumbing.

447. The library finds overnight encampments on the grounds where there is evidence of opioid use, i.e. used syringes. The library staff uses resources to remove the syringes.

448. The library has needed to invest in safety training to deal with clean up issues related to opioid use and conducted a staff training in 2017.

449. Additionally, the library has invested in training for the management and patrons experiencing opioid intoxication. In 2017, two staff members attended such training.

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450. The library also invested in better security equipment and cameras to address opioid intoxication. Its incident log reflects that one third of the library's safety issues result from potentially opioid-impaired patrons.

451. Mount Vernon's Fire Department is also touched by the opioid crisis. The Fire Department expends resources responding to overdoses, deaths, and injuries related to the opioid crisis. The City of Mount Vernon has spent resources training emergency medical personnel to respond to opioid overdoes and the Fire Department also engages in training related to this issue. The Fire Department also spends money on naloxone medication (to reverse opioid overdoses).

452. The opioid epidemic has also put significant demands on the criminal justice system, its resources, and the staff and public service employees.

453. Mount Vernon contracts with the county jail to house opioid offenders. The city provides revenues through interlocal agreements with the County in exchange for use of the County jail facility. The interlocal agreement also contains provisions where costs go up and "bed rates" apply once certain benchmarks are met triggering the need for additional funds. Mount Vernon pays the County additional funds for jail medical expenses which have dramatically increased (and coincide with the increased number of opioid users).

454. Mount Vernon Police Department is responsible for helping prevent crime, patrolling neighborhoods, responding to calls for services, investigating crimes, arresting offenders and working to solve neighborhood problems; it provides a variety of law enforcement services and outreach programs to its residents.

455. A significant portion of their time, however, is also devoted to addressing and responding to the crisis caused by Defendants.

456. In 2007, Mount Vernon Police Department responded to 182 drug-related incidents. In 2017, they number rose to 315 drug-related incidents. Notably, these numbers reflect incidents that were initially reported out as drug-related. Officers also frequently respond to calls where the underlying call out is for a different crime but the conduct has an involvement

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with drugs. For example, in 2017, officers responded to a homicide where a drug dealer was killed. In another incident, a defendant was convicted of controlled substance homicide for selling heroin to a drug court participant who died. Additionally, many individuals that are arrested at Walmart for theft have opioids or paraphernalia on their person or property. Officers also receive a lot of fraud cases where the victim's credit card is used by a drug dealer. When stolen vehicles are recovered they often contain opioids and drug paraphernalia.

457. The growing impact of opioids is also reflected in the increasing budget for narcotic testing kits. In 2007, for example, the department spent $89.52 on narcotic testing kits. In 2017, the budget rose to $1,650.89.

458. Mount Vernon police officers indicate that they encounter opioid use on a daily basis and that opioid use is common among property crime suspects and the transient population. One officer indicated that most thefts, vagrancy, disorderly, and removal calls involve someone under the influence of opioids. Another indicated that he contacts at least one person per day that has an opioid addiction.

459. As in other jurisdictions in the County, Mount Vernon officers also report an increase in the number of used syringes left out in public places.

460. The Prosecution Division of Mount Vernon's City Attorney's Office adjudicates misdemeanor violations and infractions in Mount Vernon Municipal Court. Felony crimes that occur in Mount Vernon are prosecuted by the Skagit County Prosecutor's Office. As such, felony possession of a controlled substance crimes are not handled by the Mount Vernon municipal prosecutor; however, the impact of the opioid crisis is still visible among individuals referred for misdemeanor crimes that either display signs of addiction or commit property crimes to fuel their substance abuse habits.

461. The Mount Vernon City Prosecutor reports that the opioid issue has become worse, and not better in their Court. Mount Vernon has had to spend more money to prosecute crimes and has incurred greater costs in its staffing to do so; in the 2018 budget a community

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prosecutor was provided for and the city recently hired an embedded social worker. Mount Vernon is commonly referred defendants charged with drug-related crimes (e.g., possession of drug paraphernalia).

462. The City of Mount Vernon also receives a significant number of theft cases, wherein the defendants are committing crimes to support their addictions.

463. Mount Vernon also has experienced an increase in the number of trespassing cases over time; a significant portion of those defendants appear to be in the situation they are in due to addiction-related issues.

464. The City of Mount Vernon has also incurred health care costs associated with the epidemic that are borne by the city. While Mount Vernon is not self-insured, it has paid significant amounts for both prescription opioids and opioid-related claims over the last several years.

3. The City of Sedro-Woolley is affected by the crisis.

465. The City of Sedro-Woolley has also had to deal with Defendants' misconduct, including but not limited to the following departments and divisions in Sedro-Woolley that have been directly affected by the opioid crisis: Parks & Recreation, Public Works & Operations, Solid Waste, and Sedro-Woolley Police Department.

466. As in neighboring Skagit County communities, the opioid epidemic has affected Sedro-Woolley's Public Works Operations department and its parks, in highly visible ways.

467. Particularly, public restrooms in Sedro-Woolley parks are frequently utilized for selling or using drugs. Just like other areas in Skagit County, uncapped syringes and other drug paraphernalia are routinely found in Sedro-Woolley restrooms. Sedro-Woolley Public Works employees fear getting stuck by a needle, or inhaling some form of opioid such as fentanyl, and the department has had to devote resources to training on safe handling and disposal of abandoned needles and other paraphernalia.

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468. The Public Works division is also responsible for cleaning storm drainage catch basins and street sweeping. The crews routinely discover needles that have been dumped in catch basins and discarded on roadsides.

469. Sedro-Woolley has made it a priority to routinely inspect the facilities to ensure they are safe for the public. In doing so, Sedro-Woolley has had to change its clean-up procedures and its performance of certain jobs. For example, historically, the Parks and Recreation department would clean leaves in rain gutters and debris in certain facilities by hand. Because needles are often found in gutters that were thrown onto roofs, Public Works Operations employees now utilize equipment to do so; However, as Nathan Salseina reported, needles get stuck in their equipment and "become a hazard when we are servicing the equipment and performing our daily jobs."

470. Public Works staff and Sedro-Woolley Police Department employees have had to spend time cleaning up homeless encampments in some of the larger wooded parks in Sedro-Woolley, which requires significant man power. These encampments are riddled with needles which also present a safety risk to all those who encounter them on public property.

471. At a time where resources for the parks are slim, the Sedro-Woolley Parks and Recreation Department has made operational changes to address needle clean up and vandalism issues. For example, the Parks and Recreation Department has implemented improved lighting in identified problem areas, and has expanded the resident park caretaker program which provides a residence for a caretaker to live on site and monitor activities at three of the Sedro-Woolley parks. Sedro-Woolley has noted that having a caretaker on site has significantly discouraged bad behavior.

472. The Solid Waste Division of the Public Works Department is also impacted. They are responsible for cleaning up garbage left behind from drug-related houses or curb-side garbage due to drug-related evictions. They, too, are subject to the worry and stress of possible injury due to exposure to needles every time they collect garbage throughout the city.

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473. Costs for disposal of debris has gone up. The Solid Waste Division also runs the Decant facility where street sweepings and storm water materials are collected and disposed. Rather than recycling those materials, however, they must be disposed of in a landfill. The Operations Division's costs for staff to inspect drug-suspected areas have gone up in the last two years. Further, costs for disposal of debris and costs associated with more disinfectant and sterilization supplies have increased.

474. In addition, the Sedro-Woolley Police Department (SWPD), a full-service department with seventeen sworn officers, is on the front line of the opioid epidemic and the homelessness crisis it has driven and shaped.

475. SWPD is confronted with the opioid epidemic daily. For example, SWPD officers stop vehicles during routine patrol and often they find individuals with needles in the car. On multiple occasions SWPD officers have been dispatched to suspicious vehicles and, upon arrival, found an individual passed out in the car with a needle sticking out of their arm.

476. SWPD officers respond to abandoned buildings or homes to address squatters or trespassers and find needles. Several locations in Sedro-Woolley have vulnerable adults whose homes have been taken over by opioid "squatters."

477. Law enforcement encounters opioid use even outside normal patrol duties and citizens that may not be trained and equipped to properly handle and dispose of used, uncapped, needles are encountering them. For example, when the Chief of Police, William Tucker, was at a McDonald's, he was asked by the cashier if he could take some syringes that were found in the bathroom. He was given a Ziploc baggie with needles.

478. SWPD has also had to change its policy on field testing suspected heroin. As noted above, fentanyl is a synthetic opioid that is fifty times stronger than heroin. Even tiny amounts of it can be lethal, and it can be absorbed through the skin. The DEA warned all law

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enforcement nationwide about the dangers of improperly handling fentanyl.[227] Given the risks of fentanyl exposure, SWPD now tests suspected controlled substances in controlled conditions, and uses personal protective equipment. Officers will also be required to have another partner present when testing, and Narcan or an equivalent will be carried in the event an officer is exposed to fentanyl. With additional precautions come additional costs.

479. The City of Sedro-Woolley has also incurred health care costs associated with the opioid epidemic that are borne by the city. While the city is not self-insured, it has paid significant amounts for both prescription opioids and opioid-related claims over the last several years.

4. The City of Burlington is affected by the crisis.

480. The City of Burlington has also had to deal with Defendants' misconduct, including but not limited to the following departments in the city that have been directly impacted by the crisis caused by Defendants.

481. The Parks and Recreation Department in the City of Burlington is experiencing effects of the opioid epidemic similar to its neighboring communities. The Parks and Recreation Department has safety concerns for park users and workers, as there is a continued increase of abandoned needles in the parks and open spaces. The department must also allocate resources to safely dispose of the used needles and syringes, installing sharps containers, for example, in some park bathrooms. Used syringes and other drug paraphernalia are frequently found in certain park locations (such as the Maiben park restrooms, Whitmarsh park restrooms, and certain locations at Skagit River Park).

482. In addition, the Parks and Recreation Department has seen a rise in vandalism, homelessness, and inappropriate use of the restrooms—using them as a place to sleep or to use and sell drugs—which results in safety concerns for staff and park users.

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[227] *DEA Warning to Police and the Public: Fentanyl Exposure Kills*, Drug Enforcement Administration (June 10, 2016), https://www.dea.gov/divisions/hq/2016/hq061016.shtml.

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483. The Parks and Recreation Department is confronted with rising costs to mitigate these concerns. Burlington has installed automatic door locks in restrooms, mounted cameras in parks, upgraded lighting, and redesigned areas within parks that increase visibility. Additional costs are incurred to provide extra training for staff to keep them safe and invest in proper supplies and equipment, and to clean up drug material and waste from transient encampments.

484. In addition to its parks, Burlington expends resources to safely dispose of used needles frequently found in the Burlington Public Library and on library grounds. The library and its staff have been particularly affected by the opioid epidemic.

485. While libraries are critical sources of information and social service referrals, staff are not properly trained to respond to individuals in crisis or overdose. Yet Burlington's library staff must do so frequently; multiple Burlington Public Library patrons have overdosed and passed out in the library. These incidents are traumatizing for staff. In the words of one librarian, "it's nearly impossible to describe how scary it is when someone will not wake up." Staff interacting directly with patrons in crisis can experience compassion fatigue and burnout.

486. In addition, dealing with increased incidents related to the opioid crisis takes staff away from vital library services. Time spent patrolling the facility and inspecting bathrooms for needles interrupts service at the reference desk and in library programs. Library staff frequently find bloody needles in the restrooms and sometimes have to call the facilities department because blood is all over the restroom. Furthermore, the increase in police presence and discovery of opioid paraphernalia negatively colors public perception of the library.

487. The Burlington Municipal Court is seeing a rise in criminal cases related to opioids over the past decade. In particular, the Municipal Court sees more criminal trespass and public camping violations that are related to opioid use. Opioids are playing more of a role in other cases, even when the charges are not related to controlled substances. Both the prosecutor and public defenders have experienced an increase in the number of individuals using heroin and other opioids.

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488. The Burlington Police Department encounters opioid use on a daily basis in its contacts with individuals; during a 24-hour period, Burlington police have contact with at least one person who suffers from opioid use/abuse. Officers also commonly respond to overdoses and possession of opioids is a common crime.

489. Burlington contracts with the Skagit County jail for offenders of all crimes occurring in Burlington including opioid offenders.

490. Burlington also contracts with Central Valley Ambulance Authority (CVAA) to provide emergency medical services, including naloxone distribution. CVAA is equipped with naloxone and provides it on service calls. CVAA operates in part out of the Burlington Fire Department (BFD) facilities.

491. Burlington spends emergency service resources responding to overdoses, deaths, and injuries related to opioid abuse; BFD responds to many overdoses each year. BFD also engages in training related to opioid abuse. Each BFD firefighter receives training on the administration of Narcan.

492. The City of Burlington has also incurred health care costs associated with the epidemic that are borne by the city. While the city is not self-insured, it has paid significant amounts for both prescription opioids and opioid-related claims over the last several years.

5. La Conner School District is affected by the opioid crisis.

493. The La Conner School District has also been affected by Defendants' misconduct. La Conner School District is comprised of the Swinomish Preschool, La Conner Elementary, Middle, and High School. In addition to teachers, educational assistants, counselors, principals, and administrators at the respective schools, the District also employs over thirty staff, including the Superintendent and Director of Business Operations.

494. The La Conner School District spends substantial sums and resources in addressing and responding to the opioid crisis.

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495. For example, La Conner School District principals and administrators have observed numerous ways that opioid use has affected the District. As opioid use has expanded, school administrators have observed an increase in the number of legal actions that restrict parental access to the school and children, such as restraining orders. In addition, administrators have observed an increased level of coordination with social workers.

496. Because of the opioid epidemic, La Conner School District students as young as fourth and fifth graders are being pulled into parenting roles as their own parents struggle with addiction. The guardianship of children also changes more frequently, and this creates difficulty for the school district to contact parents and keep up with emergency contacts. It also takes more effort for district personnel to determine what is going on with kids behind the scenes and determine what they can do to help them. More students are going to foster homes, which increases school absences.

497. Students are experiencing adverse childhood experiences related to opioid use. For example, one student came home to an ambulance in his driveway when his older brother overdosed.

498. Some older students, emulating their parents and other family members, bring pills to school. Skagit County high school students, including in the La Conner School District, report misusing prescription opioids: in 2014, five percent of all 10th and 12th graders reported using painkillers to get high in the thirty days prior to being surveyed.[228] In addition, ten percent of 10th graders and eight percent of 12th graders report misusing someone else's prescription in the thirty days prior to responding to the survey.[229]

499. Fully addressing the harms to the La Conner School District caused by Defendants' conduct will require a comprehensive approach, one that includes drug counselors in schools, prevention education that includes information about opioids' physical effects on the

[228] *Healthy Youth Survey Fact Sheet, Skagit County* (2014), http://adai.uw.edu/wastate/HYS/2014%20Skagit.pdf.
[229] *Id.*

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body and refusal skills, supervision and mentoring for kids when their parents are working nights, safe and supervised housing, and group treatment options. Without the resources to fund these measures, the La Conner School District will continue to be harmed by the ongoing consequences of Defendants' conduct.

6. Mount Vernon School District is affected by the opioid crisis.

500. Mount Vernon School District is also affected by the opioid epidemic. Mount Vernon School District includes six elementary schools (Little Mountain, Madison, Washington, Lincoln, Jefferson, and Centennial), two middle schools (Mount Baker, and LaVenture) and one high school (Mount Vernon High School).

501. Students at Mount Vernon schools have access to opioids. According to the 2016 Healthy Use Survey, 6.5% of 8th graders and 11.7% of 10th graders in the Mount Vernon School District reported using a prescription drug that was not prescribed to them within the last thirty days.

502. Student attitudes about use of prescription drugs are also telling. For example, in response to the 2016 Healthy Youth Survey, 8.9% of 8th graders and 12.3% of 10th graders in Mount Vernon School District reported that their friends would not have a problem using prescription drugs not prescribed to them (i.e., using prescription drugs not prescribed to them would be only "a little bit wrong" or "not at all wrong").

503. In addition to attitudes about use of prescription drugs, a number of socio-economic factors place students at risk for opioid use, including lower household income levels and housing instability. In Mount Vernon School District, 65% of students are eligible for the free or reduced lunch program and 135 students are qualified as homeless.

504. The School District spends approximately $126,540 each year transporting homeless students to their schools of origin. The school also spends approximately $20,000 on substance abuse intervention specialists, and approximately $95,000 (inclusive of benefits) for a full time social worker that serves as a resource and referral for students and families at risk for

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substance abuse. The District also pays for three full-time, in-school site coordinators who provide direct intervention with students and families struggling with issues of homelessness and poverty, which costs approximately $175,000 inclusive of benefits. The District also provides an associate registered nurse on staff who treats medical conditions related to substance abuse and substandard housing. The total annual approximate cost of these employees is $512,040. A substantial proportion of these employees' time now goes to addressing consequences of the opioid epidemic.

505. Like the La Conner School District, in order to fully abate the harms caused by Defendants' conduct, the Mount Vernon School District needs additional resources to finance support systems to help students affected by the opioid epidemic.

I. No Federal Agency Action, Including by the FDA, Can Provide the Relief Plaintiffs Seek Here.

506. The injuries Plaintiffs have suffered and will continue to suffer cannot be addressed by agency or regulatory action. There are no rules the FDA could make or actions the agency could take that would provide Plaintiffs the relief they seek in this litigation.

507. Even if prescription opioids were entirely banned today or only used for the intended purpose, millions of Americans, including Skagit County residents, would remain addicted to opioids, and overdoses will continue to claim lives. The Sheriff's Department will continue to spend extraordinary resources combatting illegal opioid sales, and the Prosecutor's Office and County and city courts will remain burdened with opioid-related crimes and dependency hearings. Social services and public health efforts will be stretched thin.

508. Regulatory action would do nothing to compensate Plaintiffs for the money and resources they have already expended addressing the impacts of the opioid epidemic and the resources it will need in the future. Only this litigation has the ability to provide Plaintiffs with the relief they seek.

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509. Furthermore, the costs Plaintiffs have incurred in responding to the opioid crisis and in rendering public services described above are recoverable pursuant to the causes of actions raised by Plaintiffs. Defendants' misconduct alleged herein is not a series of isolated incidents, but instead the result of a sophisticated and complex marketing scheme over the course of more than twenty years that has caused a substantial and long-term burden on the municipal services provided by Plaintiffs. In addition, the public nuisance created by Defendants and the Plaintiffs' requested relief in seeking abatement further compels Defendants to reimburse and compensate Plaintiffs for the substantial resources they have expended to address the opioid crisis.

V. CLAIMS FOR RELIEF

COUNT ONE — VIOLATIONS OF THE WASHINGTON CONSUMER PROTECTION ACT, RCW 19.86, *ET SEQ.*

510. Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, and Burlington repeat, reassert, and incorporate the allegations contained above as if fully set forth herein.

511. The Washington Consumer Protection Act is codified at RCW 19.86 *et seq*. (CPA). The CPA establishes a comprehensive framework for redressing the violations of applicable law, and municipalities of Washington State like Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, and Burlington can enforce the CPA and recover damages. RCW 19.86.090. The conduct at issue in this case falls within the scope of the CPA.

512. The CPA prohibits unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. Defendants engaged and continue to engage in the same pattern of unfair methods of competition, and unfair and/or deceptive conduct pursuant to a common practice of misleading the public regarding the purported benefits and risks of opioids.

513. Manufacturing Defendants, at all times relevant to this Complaint, directly and/or through their control of third parties, violated the CPA by making unfair and/or deceptive

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representations about the use of opioids to treat chronic and non-cancer pain, including to physicians and consumers in Skagit County, Mount Vernon, Sedro-Woolley, and Burlington. Each Manufacturing Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the purported benefits and risks of opioids. In addition, each Manufacturing Defendant's silence regarding the full risks of opioid use constitutes deceptive conduct prohibited by the CPA.

514. Distributor Defendants, at all times relevant to this Complaint, directly and/or through their control of third parties, violated the CPA by making unfair and/or deceptive representations about their compliance with their obligations to maintain effective controls against diversion of prescription opioids and to report suspicious orders. Distributor Defendants concealed the extent of their opioid distribution in order to avoid the issuance of restrictive quotas, and manipulated the political process to shield themselves from enforcement actions that would have stopped shipments of opioids.

515. These unfair methods of competition and unfair and/or deceptive acts or practices in the conduct of trade or commerce were reasonably calculated to deceive Plaintiffs and their consumers, and did in fact deceive Plaintiffs and their consumers. Each Manufacturing Defendant's misrepresentations, concealments, and omissions continue to this day.

516. Plaintiffs have paid money for health care costs associated with prescription opioids for chronic pain. Plaintiffs have also paid significant sums of money treating those covered by its health insurance for other opioid-related health costs. The Defendants' misrepresentations have further caused Plaintiffs to spend substantial sums of money on increased law enforcement, emergency services, social services, public safety, and other human services, as described above.

517. But for these unfair methods of competition and unfair and/or deceptive acts or practices in the conduct of trade or commerce, Plaintiffs would not have incurred the costs related to the epidemic caused by Defendants, as fully described above.

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518. Logic, common sense, justice, policy, and precedent indicate Manufacturing Defendants' unfair and deceptive conduct has caused the damage and harm complained of herein. Manufacturing Defendants knew or reasonably should have known that their statements regarding the risks and benefits of opioids were false and misleading, and that their statements were causing harm. Distributor Defendants knew or reasonably should have known that the proliferation of prescription opioids was causing damage to the County. Thus, the harms caused by Defendants' unfair and deceptive conduct to Plaintiffs were reasonably foreseeable, including the financial and economic losses incurred by Plaintiffs.

519. Furthermore, Skagit County, Mount Vernon, Sedro-Woolley, and Burlington bring this cause of action in their sovereign capacity for the benefit of the State of Washington. The CPA expressly authorizes local governments to enforce their provisions and to recover damages for violations of the CPA, and this action is brought to promote the public welfare of the state and for the common good of the state.

520. As a direct and proximate cause of each Defendant's unfair and deceptive conduct, (i) Plaintiffs have sustained and will continue to sustain injuries, and (ii) pursuant to RCW 19.86.090, Plaintiffs are entitled to actual and treble damages in amounts to be determined at trial, attorneys' fees and costs, and all other relief available under the CPA.

521. The Court should also grant injunctive relief enjoining Defendants from future violations of the CPA. Defendants' actions, as complained of herein, constitute unfair competition or unfair, deceptive, or fraudulent acts or practices in violation of the CPA.

COUNT TWO — PUBLIC NUISANCE

522. Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, Burlington, La Conner School District, and Mount Vernon School District repeat, reassert, and incorporate the allegations contained above as if fully set forth herein.

523. Pursuant to RCW 7.48.010, an actionable nuisance is defined as, *inter alia*, "whatever is injurious to health or indecent or offensive to the senses . . ."

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524. Pursuant to RCW 7.48.130, "A public nuisance is one which affects equally the rights of an entire community or neighborhood, although the extent of the damage may be unequal."

525. Pursuant to Skagit County Code Chapter 14.44.120(3), "A violation is detrimental to the public health, safety, and welfare and is a public nuisance. A public nuisance is a continuing offense against the order and economy of Skagit County and is subject to abatement both under this Chapter and RCW Chapter 7.48."

526. Pursuant to Mount Vernon City Code Ch. 8.08.030, "A nuisance consists of unlawfully doing an act, or omitting to perform a duty, which acts or omissions either annoy, injure or endanger the comfort, repose, health or safety of others, offends decency, or unlawfully interferes with, obstructs or tends to obstruct or render dangerous for passage any lake or navigable river, bay, stream, canal or basin, or any public park, square, street or highway; or in any way renders persons insecure in life or the use of property."

527. Pursuant to Sedro-Woolley Municipal Code Ch. 18.10.020(A), "All civil code violations hereby are determined to be detrimental to the public health, safety, and environment and are hereby declared public nuisances."

528. Pursuant to Burlington Municipal Code Ch. 14.806.080(D), "Any condition relating to grading, storm water, drainage or erosion which creates a present or imminent danger, or which is likely to create a danger in the event of a design storm, to the public health, safety or welfare, the environment, or public or private property is hereby declared to be a public nuisance."

529. Residents of Skagit County, Mount Vernon, Sedro-Woolley, and Burlington have a right to be free from conduct that endangers their health and safety. Yet Defendants have engaged in conduct which endangers or injures the health and safety of the residents of Skagit County, Mount Vernon, Sedro-Woolley, and Burlington by their production, promotion, distribution, and marketing of opioids for use by residents of Skagit County, Mount Vernon,

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Sedro-Woolley, and Burlington and in a manner that substantially interferes with the welfare of Plaintiffs' communities.

530. Each Defendant has created or assisted in the creation of a condition that is injurious to the health and safety of Plaintiffs and their residents, and interferes with the comfortable enjoyment of life and property of entire communities and/or neighborhoods in Skagit County, Mount Vernon, Sedro-Woolley, and Burlington.

531. Defendants' conduct has directly caused deaths, serious injuries, and a severe disruption of the public peace, order, and safety. Defendants' conduct is ongoing and continues to produce permanent and long-lasting damage.

532. The health and safety of the residents of Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, including those who use, have used, or will use opioids, as well as those affected by others' opioid use, are matters of substantial public interest and of legitimate concern to the Plaintiffs' citizens and its residents.

533. Defendants' conduct has affected and continues to affect a substantial number of people within Skagit County, Mount Vernon, Sedro-Woolley, and Burlington and is likely to continue causing significant harm.

534. But for Defendants' actions, opioid use—and, ultimately, misuse and abuse—would not be as widespread as it is today, and the opioid epidemic that currently exists would have been averted.

535. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair and deceptive conduct has caused the damage and harm complained of herein. Manufacturing Defendants knew or reasonably should have known that their statements regarding the risks and benefits of opioids were false and misleading, and that their false and misleading statements were causing harm from their continued production and marketing of opioids. Distributor Defendants knew that the widespread distribution of opioids would endanger the health and safety of residents of Skagit County, Mount Vernon, Sedro-Woolley, and Burlington. Thus, the

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public nuisance caused by Defendants to Skagit County, Mount Vernon, Sedro-Woolley, and Burlington was reasonably foreseeable, including the financial and economic losses incurred by each of these municipalities.

536. Furthermore, Skagit County, Mount Vernon, Sedro-Woolley, and Burlington bring this cause of action in their sovereign capacity for the benefit of the State of Washington. The applicable RCW with respect to a public nuisance expressly prohibits the conduct complained of herein, and this action is brought to promote the public welfare of the state and for the common good of the state.

537. In addition, engaging in any business in defiance of a law regulating or prohibiting the same is a nuisance per se under Washington law. Each Defendant's conduct described herein of deceptively marketing or excessively distributing opioids violates RCW 7.48.010 and therefore constitutes a nuisance per se.

538. As a direct and proximate cause of Defendants' conduct creating or assisting in the creation of a public nuisance, Plaintiffs and their residents have sustained and will continue to sustain substantial injuries.

539. Pursuant to RCW 7.48.020, Skagit County, Mount Vernon, Sedro-Woolley, Burlington, La Conner School District, and Mount Vernon School District request an order providing for abatement of the public nuisance that each Defendant has created or assisted in the creation of, and enjoining Defendants from future violations of RCW 7.48.010.

540. Pursuant to the applicable County and City Codes set forth above, Plaintiffs also seek the maximum statutory and civil penalties permitted by law as a result of the public nuisance created by Defendants.

COUNT THREE — NEGLIGENCE

541. Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, and Burlington repeat, reassert, and incorporate the allegations contained above as if fully set forth herein.

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542. Under Washington law, a cause of action arises for negligence when a defendant owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury. *Iwai v. State*, 129 Wn. 2d 84, 96, 915 P.2d 1089 (1996).

543. Each Defendant owed a duty of care to Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

544. In violation of this duty, Defendants failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids in Skagit County, Mount Vernon, Sedro-Woolley, and Burlington by misrepresenting the risks and benefits associated with opioids and by distributing dangerous quantities of opioids.

545. As set forth above, Manufacturing Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations made by Defendants violated the duty of care to Skagit County, Mount Vernon, Sedro-Woolley, and Burlington.

546. Distributor Defendants negligently distributed enormous quantities of potent narcotics and failed to report such distributions. Distributor Defendants violated their duty of care by moving these dangerous products into Skagit County, Mount Vernon, Sedro-Woolley, and Burlington in such quantities, facilitating diversion, misuse, and abuse of opioids.

547. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, Plaintiffs have suffered and will continue to suffer harm, and are entitled to damages in an amount determined at trial.

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COUNT FOUR — GROSS NEGLIGENCE

548. Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, and Burlington repeat, reassert, and incorporate the allegations contained above as if fully set forth herein.

549. As set forth above, each Defendant owed a duty of care to Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

550. In violation of this duty, each Defendant failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids in Skagit County, Mount Vernon, Sedro-Woolley, and Burlington by misrepresenting the risks and benefits associated with opioids.

551. In addition, each Defendant knew or should have known, and/or recklessly disregarded, that the opioids they manufactured, promoted, and distributed were being used for unintended uses.

552. For instance, Defendants failed to exercise slight care to Skagit County, Mount Vernon, Sedro-Woolley, and Burlington by, *inter alia*, failing to take appropriate action to stop opioids from being used for unintended purposes. Furthermore, despite each Defendant's actual or constructive knowledge of the wide proliferation of prescription opioids in Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, Defendants took no action to prevent the abuse and diversion of these drugs. In fact, Manufacturing Defendants promoted and actively targeted doctors and their patients through training their sales representatives to encourage doctors to prescribe more opioids.

553. Manufacturing Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and

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falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations made by Manufacturing Defendants violated the duty of care to Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, in a manner that is substantially and appreciably greater than ordinary negligence.

554. Distributor Defendants continued to funnel enormous quantities of opioids into Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, long after they knew that these products were being misused, abused, and diverted. By permitting the movement of such excessive quantities of dangerous narcotics into Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, Distributor Defendants endangered the health and safety of Plaintiffs' residents, in a manner that is substantially and appreciably greater than ordinary negligence.

555. As a direct and proximate cause of each Defendant's gross negligence, Skagit County, Mount Vernon, Sedro-Woolley, and Burlington have suffered and will continue to suffer harm, and are entitled to damages in an amount determined at trial.

COUNT FIVE — UNJUST ENRICHMENT

556. Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, and Burlington repeat, reassert, and incorporate the allegations contained above as if fully set forth herein.

557. Each Defendant was required to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

558. Rather than prevent or mitigate the wide proliferation of opioids into Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, each Defendant instead chose to place its monetary interests first, and each Defendant profited from prescription opioids sold in Skagit County, Mount Vernon, Sedro-Woolley, and Burlington.

559. Each Defendant also failed to maintain effective controls against the unintended and illegal use of the prescription opioids it manufactured or distributed, again choosing instead to place its monetary interests first.

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560. Each Defendant therefore received a benefit from the sale and distribution of prescription opioids to and in Skagit County, Mount Vernon, Sedro-Woolley, and Burlington, and these Defendants have been unjustly enriched at the expense of Skagit County, Mount Vernon, Sedro-Woolley, and Burlington.

561. As a result, Plaintiffs are entitled to damages on its unjust enrichment claim in an amount to be proven at trial.

COUNT SIX — VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, *ET SEQ.*

562. Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, and Burlington hereby incorporate by reference the allegations contained in the preceding paragraphs of this complaint.

563. This claim is brought by Skagit County and the Cities of Mount Vernon, Sedro-Woolley, and Burlington against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961, *et seq*.

564. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, "a legal or beneficial interest in property."

565. Plaintiffs are "persons," as that term is defined in 18 U.S.C. § 1961(3), and have standing to sue as they were and are injured in their business and/or property as a result of the Defendants' wrongful conduct described herein.

566. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . " 18 U.S.C. § 1962(c).

567. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

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568. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

A. Description of the Defendants' Enterprises

569. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

570. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

571. Defendants formed two such association-in-fact enterprises—referred to herein as "the Promotion Enterprise" and "the Diversion Enterprise."

572. The Promotion Enterprise consists of the Manufacturing Defendants, Front Groups, and KOLs. In particular, the Enterprise consists of (a) Defendant Purdue, including its employees and agents, (b) Defendant Endo, including its employees and agents, (c) Defendant Janssen, including its employees and agents, (d) Defendant Cephalon, including its employees and agents, (e) Defendant Actavis, including its employees and agents, and (f) Defendant Mallinckrodt, including its employees and agents (collectively, "Manufacturing Defendants"); certain front groups described above, including but not limited to (a) the American Pain Foundation, including its employees and agents, (b) the American Academy of Pain Medicine, including its employees and agents, and (c) the American Pain Society, including its employees and agents (collectively, the "Front Groups"); and certain Key Opinion Leaders, including but not limited to (a) Dr. Russell Portenoy, (b) Dr. Perry Fine, (c) Dr. Lynn Webster, and (d) Dr. Scott Fishman (collectively, the "KOLs"). The entities in the Promotion Enterprise acted in concert to create demand for prescription opioids.

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573. Alternatively, each of the above-named Manufacturing Defendants and Front Groups constitutes a single legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the members of the enterprise conducted a pattern of racketeering activity. The separate legal status of each member of the Enterprise facilitated the fraudulent scheme and provided a hoped-for shield from liability for Defendants and their co-conspirators.

574. Alternatively, each of the Manufacturing Defendants, together with the Distributor Defendants, the Front Groups, and the KOLs, constitute separate, associated-in-fact Enterprises within the meaning of 18 U.S.C. § 1961(4).

575. The Diversion Enterprise consists of all Defendants. In particular, the Enterprise consists of (a) Defendant Purdue, including its employees and agents, (b) Defendant Endo, including its employees and agents, (c) Defendant Janssen, including its employees and agents, (d) Defendant Cephalon, including its employees and agents, (e) Defendant Actavis, including its employees and agents, (f) Defendant Mallinckrodt, including its employees and agents, (g) Defendant AmerisourceBergen, including its employees and agents, (h) Defendant Cardinal Health, including its employees and agents, and (i) Defendant McKesson, including its employees and agents (collectively, "Defendants").

576. The CSA and its implementing regulations require all manufacturers and distributors of controlled substances, including opioids, to maintain a system to identify and report suspicious orders, including orders of unusual size or frequency, or orders deviating from a normal pattern, and maintain effective controls against diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. §1301.74(b). The Manufacturing Defendants and the Distributor Defendants alike are required to become "registrants" under the CSA, 21 U.S.C. § 823(a)-(b), and its implementing regulations, which provide that "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance. . . shall obtain a registration[.]" 21 C.F.R. § 1301.11(a). Defendants' duties as registrants include reporting suspicious orders of controlled substances, which are defined as including "orders of unusual

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size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

577. The Manufacturing Defendants carried out the Diversion Enterprise by incentivizing and supplying suspicious sales of opioids, despite their knowledge that their opioids were being diverted to illicit use, and by failing to notify the DEA of such suspicious orders as required by law. The Distributor Defendants carried out the Diversion Enterprise by failing to maintain effective controls against diversion, intentionally evading their obligation to report suspicious orders to the DEA, and conspiring to prevent limits on the prescription opioids they were oversupplying to communities like Plaintiffs.

578. The Promotion Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to sell highly addictive opioids for treatment of chronic pain while knowing that opioids have little or no demonstrated efficacy for such pain and have significant risk of addiction, overdose, and death.

579. The Distribution Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to distribute highly addictive opioids in quantities that far exceeded amounts that could reasonably be considered medically necessary.

580. To accomplish these purposes, the Promotion Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for Defendants' opioid medications (the "Promotion Scheme"), and the Diversion Enterprise carried out a scheme to systematically disregard, avoid, or frustrate the monitoring and reporting requirements intended to prevent the widespread distribution of dangerous controlled substances (the "Diversion Scheme"). The Promotion Scheme and the Diversion Scheme are collectively referred to as the "Schemes."

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B. The Enterprises Sought to Fraudulently Increase Defendants' Profits and Revenues

581. At all relevant times, each Defendant was aware of the conduct of the Enterprises, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales and distribution of prescription opioids. In addition, the Front Groups and KOLs received direct payments from the Manufacturing Defendants in exchange for their role in the Promotion Enterprise, and to advance the Promotion Enterprise's fraudulent marketing scheme.

582. The Enterprises engaged in, and their activities affected, interstate and foreign commerce because they involved commercial activities across state boundaries, including but not limited to: (1) the marketing, promotion, and distribution of prescription opioids; (2) advocacy at the state and federal level for change in the law governing the use and prescription of prescription opioids; (3) the issuance of prescriptions and prescription guidelines for opioids; (4) the issuance of fees, bills, and statements demanding payment for prescriptions of opioids; (5) payments, rebates, and chargebacks between Defendants; and (6) the creation of documents, reports, and communications related to Defendants' reporting requirements under the CSA and its implementing regulations.

583. The persons engaged in the Enterprises are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. With respect to the Promotion Enterprise, each Manufacturing Defendant funded and directed the operations of the KOLs and the Front Groups; in fact, the board of directors of each of the Front Groups are and were full of doctors who were on the Manufacturing Defendants' payrolls, either as consultants or speakers at medical events. Moreover, each Manufacturing Defendant coordinated and, at times, co-funded their activities in furtherance of the goals of the Enterprise. This coordination can also be inferred through the consistent misrepresentations described below. With respect to the Diversion Enterprise, Defendants were financially linked through a system of payments, rebates, and chargebacks.

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584. In the Promotion Enterprise, there is regular communication between each Manufacturing Defendant, each of the Front Groups, and each KOL in which information regarding the Defendants' scheme to increase opioid prescriptions is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Manufacturing Defendants, the Front Groups, and the KOL share information regarding the operation of the Promotion Enterprise.

585. In the Diversion Enterprise, there is regular communication between each Defendant in which information regarding the Defendants' scheme to oversupply opioids and avoid restrictive regulations or quotas is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants share information regarding the operation of the Diversion Enterprise.

586. The Enterprises functioned as continuing units for the purposes of executing the Schemes, and when issues arose during the Schemes, each member of the Enterprises agreed to take actions to hide the Schemes and the existence of the Enterprises.

587. Each Defendant participated in the operation and management of the Enterprises by directing its affairs as described herein.

588. While Defendants participate in, and are members of, the Enterprises, they have an existence separate from the Enterprises, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.

589. Each Manufacturing Defendant orchestrated the affairs of the Promotion Enterprise and exerted substantial control over the Promotion Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (2) employing sales representatives to promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Promotion Scheme; (4) employing doctors to serve

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as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (6) sponsoring CME programs that claimed that opioid therapy has been shown to reduce pain and depressive symptoms; (7) supporting and sponsoring guidelines indicating that opioid medications are effective and can restore patients' quality of life; (8) retaining KOLs to promote the use of opioids; and (9) concealing the true nature of their relationships with the other members of the Promotion Scheme, and the Promotion Enterprise, including the Front Groups and the KOLs.

590. The Front Groups orchestrated the affairs of the Promotion Enterprise and exerted substantial control over the Promotion Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids described herein; (2) holding themselves out as independent advocacy groups, when in fact their operating budgets are entirely comprised of contributions from opioid drug manufacturers; (3) publishing treatment guidelines that advised the prescription of opioids; (4) sponsoring medical education programs that touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks; and (5) concealing the true nature of their relationship with the other members of the Promotion Enterprise.

591. The KOLs orchestrated the affairs of the Promotion Enterprise and exerted substantial control over the Promotion Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids; (2) holding themselves out as independent, when in fact they are systematically linked to and funded by opioid drug manufacturers; and (3) concealing the true nature of their relationship with the other members of the Promotion Enterprise.

592. Without the willing participation of each member of the Promotion Enterprise, the Promotion Scheme and the Promotion Enterprise's common course of conduct would not have been successful.

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593. Each Distributor Defendant orchestrated the affairs of the Diversion Enterprise and exerted substantial control over the Diversion Enterprise by, at least: (1) refusing or failing to identify, investigate, or report suspicious orders of opioids to the DEA; (2) providing the Manufacturing Defendants with data regarding their prescription opioid sales, including purchase orders and ship notices; (3) accepting payments from the Manufacturing Defendants in the form of rebates and/or chargebacks; (4) filling suspicious orders for prescription opioids despite having identified them as suspicious and knowing opioids were being diverted into the illicit drug market; (5) working with other members of the Enterprise through groups like the Healthcare Distribution Alliance to ensure the free flow of opioids, including by supporting limits on the DEA's ability to use immediate suspension orders; and (6) concealing the true nature of their relationships with the other members of the Diversion Enterprise.

594. Each Manufacturing Defendant orchestrated the affairs of the Diversion Enterprise and exerted substantial control over the Diversion Enterprise by, at least: (1) refusing or failing to identify, investigate, or report suspicious orders of opioids to the DEA; (2) obtaining from the Distributor Defendants data regarding their prescription opioid sales, including purchase orders and ship notices; (3) providing payments to the Distributor Defendants in the form of rebates and/or chargebacks; (4) working with other members of the Diversion Enterprise through groups like the Healthcare Distribution Alliance to ensure the free flow of opioids, including by supporting limits on the DEA's ability to use immediate suspension orders; and (5) concealing the true nature of their relationships with the other members of the Diversion Enterprise.

595. Without the willing participation of each member of the Diversion Enterprise, the Diversion Scheme and the Diversion Enterprise's common course of conduct would not have been successful.

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C. Predicate Acts: Mail and Wire Fraud

596. To carry out, or attempt to carry out, the Schemes, the members of the Enterprises, each of whom is a person associated-in-fact with the Enterprises, did knowingly conduct or participate in, directly or indirectly, the affairs of the Enterprises through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

597. Specifically, the members of the Enterprises have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

598. The multiple acts of racketeering activity which the members of the Enterprises committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

599. The racketeering activity was made possible by the Enterprises' regular use of the facilities, services, distribution channels, and employees of the Enterprises.

600. The members of the Enterprises participated in the Schemes by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

601. The members of the Enterprises used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their Schemes through common misrepresentations, concealments, and material omissions.

602. In devising and executing the illegal Schemes, the members of the Enterprises devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs and the public to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

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603. For the purpose of executing the illegal Schemes, the members of the Enterprises committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal Schemes.

604. The Enterprises' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

A. Mail Fraud: The members of the Enterprises violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling and distributing excessive quantities of highly addictive opioids.

B. Wire Fraud: The members of the Enterprises violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling and distributing excessive quantities of highly addictive opioids.

605. The Manufacturing Defendants falsely and misleadingly used the mails and wires in violation of 18 U.S.C. § 1341 and § 1343. Illustrative and non-exhaustive examples include the following: Defendant Purdue's (1) May 31, 1996 press release announcing the release of OxyContin and indicating that the fear of OxyContin's addictive properties was exaggerated; (2) 1990 promotional video in which Dr. Portenoy, a paid Purdue KOL, understated the risk of opioid addiction; (3) 1998 promotional video which misleadingly cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (4) statements made on its 2000 "Partners Against Pain" website which claimed that the addiction risk of OxyContin was very low; (5) literature distributed to physicians which misleadingly cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (6) August 2001 statements to Congress by Purdue Executive Vice President and Chief Operating Officer Michael Friedman regarding the value of OxyContin in treating chronic pain; (7) patient brochure entitled "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain" indicating that OxyContin is non-addicting; (8) 2001 statement by Senior Medical Director for Purdue, Dr. David Haddox, indicating that the 'legitimate' use of OxyContin would not result in addiction; (9) multiple sales

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representatives' communications regarding the low risk of addiction associated with opioids; (10) statements included in promotional materials for opioids distributed to doctors via the mail and wires; (11) statements in a 2003 Patient Information Guide distributed by Purdue indicating that addiction to opioid analgesics in properly managed patients with pain has been reported to be rare; (12) telephonic and electronic communications to doctors and patients indicating that signs of addiction in the case of opioid use are likely only the signs of under-treated pain; (13) statements in Purdue's Risk Evaluation and Mitigation Strategy for OxyContin indicating that drug-seeking behavior on the part of opioid patients may, in fact, be pain-relief seeking behavior; (14) statements made on Purdue's website and in a 2010 "Dear Healthcare Professional" letter indicating that opioid dependence can be addressed by dosing methods such as tapering; (15) statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for opioids for chronic pain; (16) statements on its website that abuse-resistant products can prevent opioid addiction; (17) statements made in a 2012 series of advertisements for OxyContin indicating that long-term opioid use improves patients' function and quality of life; (18) statements made in advertising and a 2007 book indicating that pain relief from opioids improve patients' function and quality of life; (19) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (20) electronic and telephonic communications concealing its relationship with the other members of the Enterprises.

606. Defendant Endo Pharmaceuticals, Inc. also made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made, beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that patients who take opioids as prescribed usually do not become addicted; (2) statements made on another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do not become addicted to opioid medications; (3) statements in pamphlets and publications described by Endo indicating that most people who take opioids for pain relief do not develop an

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addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction; (5) statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering; (6) statements made on its website, PainKnowledge.com, that opioid dosages could be increased indefinitely; (7) statements made in a publication entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" suggesting that opioid doses can be increased indefinitely; (8) electronic and telephonic communications to its sales representatives indicating that the formula for its medicines is 'crush resistant;' (9) statements made in advertisements and a 2007 book indicating that pain relief from opioids improves patients' function and quality of life; (10) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (11) telephonic and electronic communications concealing its relationship with the other members of the Enterprises.

607. Defendant Janssen made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements on its website, PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated; (2) statements in a 2009 patient education guide claiming that opioids are rarely addictive when used properly; (3) statements included on a 2009 Janssen-sponsored website promoting the concept of opioid pseudoaddiction; (4) statements on its website, PrescribeResponsibly.com, advocating the concept of opioid pseudoaddiction; (5) statements on its website, PrescribeResponsibly.com, indicating that opioid addiction can be managed; (6) statements in its 2009 patient education guide indicating the risks associated with limiting the dosages of pain medicines; (7) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (8) telephonic and electronic communications concealing its relationship with the other members of the Enterprises.

608. The American Academic of Pain Medicine made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made in a

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2009 patient education video entitled "Finding Relief: Pain Management for Older Adults" indicating the opioids are rarely addictive; and (2) telephonic and electronic communications concealing its relationship with the other members of the Promotion Enterprise.

609. The American Pain Society Quality of Care Committee made a number of false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) a May 31, 1996 press release in which the organization claimed there is very little risk of addiction from the proper use of drugs for pain relief; and (2) telephonic and electronic communications concealing its relationship with the other members of the Promotion Enterprise.

610. The American Pain Foundation ("APF") made a number of false and misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made by an APF Executive Director to Congress indicating that opioids only rarely lead to addiction; (2) statements made in a 2002 amicus curiae brief filed with an Ohio appeals court claiming that the risk of abuse does not justify restricting opioid prescriptions for the treatment of chronic pain; (3) statements made in a 2007 publication entitled "Treatment Options: A Guide for People Living with Pain" indicating that the risks of addiction associated with opioid prescriptions have been overstated; (4) statements made in a 2002 court filing indicating that opioid users are not "actual addicts"; (5) statements made in a 2007 publication entitled "Treatment Options: A Guide for People Living with Pain" indicating that even physical dependence on opioids does not constitute addiction; (6) claims on its website that there is no ceiling dose for opioids for chronic pain; (7) statements included in a 2011 guide indicating that opioids can improve daily function; and (8) telephonic and electronic communications concealing its relationship with the other members of the Promotion Enterprise.

611. The KOLs, including Drs. Russell Portenoy, Perry Fine, Scott Fishman, and Lynn Webster, made a number of misleading statements in the mail and wires in violation of 18 U.S.C. § 1341 and § 1343, described above, including statements made by Dr. Portenoy in a promotional video indicating that the likelihood of addiction to opioid medications is extremely

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low. Indeed, Dr. Portenoy has since admitted that his statements about the safety and efficacy of opioids were false.

612. The Manufacturing Defendants and Distributor Defendants falsely and misleadingly used the mails and wires in violation of 18 U.S.C. § 1341 and § 1343. Illustrative and non-exhaustive examples include the following: (1) the transmission of documents and communications regarding the sale, shipment, and delivery of excessive quantities of prescription opioids, including invoices and shipping records; (2) the transmission of documents and communications regarding their requests for higher aggregate production quotas, individual manufacturing quotas, and procurement quotas; (3) the transmission of reports to the DEA that did not disclose suspicious orders as required by law; (4) the transmission of documents and communications regarding payments, rebates, and chargebacks; (5) the transmission of the actual payments, rebates, and chargebacks themselves; (6) correspondence between Defendants and their representatives in front groups and trade organizations regarding efforts to curtail restrictions on opioids and hobble DEA enforcement actions; (7) the submission of false and misleading certifications required annually under various agreements between Defendants and federal regulators; and (8) the shipment of vast quantities of highly addictive opioids. Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

613. In addition, the Distributor Defendants misrepresented their compliance with laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion into the illicit market. At the same time, the Distributor Defendants misrepresented the effectiveness of their monitoring programs, their ability to detect suspicious orders, their commitment to preventing diversion of prescription opioids, and their compliance with regulations regarding the identification and reporting of suspicious orders of prescription opioids.

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614. The mail and wire transmissions described herein were made in furtherance of Defendants' Schemes and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them; increase the prescription rate for opioid medications; and popularize the misunderstanding that the risk of addiction to prescription opioids is low when used to treat chronic pain, and to deceive regulators and the public regarding Defendants' compliance with their obligations to identify and report suspicious orders of prescription opioids, while Defendants intentionally enabled millions of prescription opioids to be deposited into communities across the United States, including in Skagit County, Mount Vernon, Sedro-Woolley, and Burlington. Defendants' scheme and common course of conduct was intended to increase or maintain high quotas for the manufacture and distribution of prescription opioids and their corresponding high profits for all Defendants.

615. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of predicate acts of mail and/or wire fraud, including certain specific fraudulent statements and specific dates upon which, through the mail and wires, Defendants engaged in fraudulent activity in furtherance of the Schemes.

616. The members of the Enterprises have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the members of the Enterprises conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants and the members of the Enterprises in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or

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minimize losses for the Defendants and their named and unnamed co-conspirators throughout the illegal scheme and common course of conduct.

617. The members of the Enterprises aided and abetted others in the violations of the above laws.

618. To achieve their common goals, the members of the Enterprises hid from Plaintiffs and the public: (1) the fraudulent nature of the Manufacturing Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with prescription opioids; (3) the fraudulent nature of the Distributor Defendants' representations regarding their compliance with requirements to maintain effective controls against diversion and report suspicious orders of opioids; and (4) the true nature of the relationship between the members of the Enterprises.

619. Defendants and each member of the Enterprises, with knowledge and intent, agreed to the overall objectives of the Schemes and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprises and their co-conspirators had to agree to conceal their fraudulent scheme.

620. The members of the Enterprises knew, and intended that, Plaintiffs and the public would rely on the material misrepresentations and omissions made by them and suffer damages as a result.

621. As described herein, the members of the Enterprises engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiffs and the public based on their misrepresentations and omissions.

622. The predicate acts also had the same or similar results, participants, victims, and methods of commission.

623. The predicate acts were related and not isolated events.

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624. The true purposes of Defendants' Schemes were necessarily revealed to each member of the Enterprises. Nevertheless, the members of the Enterprises continued to disseminate misrepresentations regarding the nature of prescription opioids and the functioning of the Schemes.

625. Defendants' fraudulent concealment was material to Plaintiffs and the public. Had the members of the Enterprises disclosed the true nature of prescription opioids and their excessive distribution, Skagit County, Mount Vernon, Sedro-Woolley, and Burlington would not have acted as they did or incurred the substantial costs in responding to the crisis caused by Defendants' conduct.

626. The pattern of racketeering activity described above is currently ongoing and open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering activity.

D. Plaintiffs Have Been Damaged by Defendants' RICO Violations

627. By reason of, and as a result of the conduct of the Enterprises and, in particular, their patterns of racketeering activity, Plaintiffs have been injured in their business and/or property in multiple ways, including but not limited to increased health care costs, increased human services costs, costs related to dealing with opioid-related crimes and emergencies, and other public safety costs, as fully described above.

628. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiffs and the public, and the County is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. § 1964(c).

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Skagit County, Mount Vernon, Sedro-Woolley, Burlington, La Conner School District, and Mount Vernon School District respectfully request the Court order the following relief:

A. An Order that the conduct alleged herein violates the Washington CPA;

B. An Order that Plaintiffs are entitled to treble damages pursuant to the Washington CPA;

C. An Order that the conduct alleged herein constitutes a public nuisance under Washington law, including under RCW 7.48 *et seq.*;

D. An Order that Defendants abate the public nuisance that they caused;

E. An Order that Defendants are liable for civil and statutory penalties to the fullest extent permissible under Washington law for the public nuisance they caused, including under the applicable County and City Codes governing public nuisances;

F. An Order that Defendants are negligent under Washington law;

G. An Order that Defendants are grossly negligent under Washington law;

H. An Order that Defendants have been unjustly enriched at Plaintiffs' expense under Washington law;

I. An Order that Defendants' conduct constitutes violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq.*;

J. An Order that Plaintiffs are entitled to recover all measure of damages permissible under the statutes identified herein and under common law;

K. An Order that Defendants are enjoined from the practices described herein;

L. An Order that judgment be entered against Defendants in favor of Plaintiffs;

M. An Order that Plaintiffs are entitled to attorneys' fees and costs pursuant to any applicable provision of law, including but not limited to under the Washington CPA; and

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N. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury on all claims and of all issues so triable.

DATED this 25th day of May, 2018.

SKAGIT COUNTY

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CERTIFICATE OF SERVICE

I certify that on May 25, 2018, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all parties of record.

s/Derek W. Loeser
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